State of California—Health and Human Services Agency

Committee for the Protection of Human Subjects

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

GAVIN NEWSOM
Governor

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS (CPHS)
CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY (CalHHS)

Members
Juan Ruiz, MD, DrPH, MPH, Chair
Larry Dickey, MD, MPH, Vice Chair
Alicia Bazzano, MD, PhD
Maria Dinis, PhD, MSW
Catherine Hess, PhD
Carrie Kurtural, JD
Laura Lund, MA
Philip Palacio, EdD, MS
John Schaeuble, PhD, MS

Remote Attendees
Philip Palacio, EdD, MS
Alicia Bazzano, MD, PhD
Larry Dickey, MD, MPH

Alternate Member
Millard Murphy, JD
Lois Lowe, PhD

Administrator
Lucila Martinez

Friday, August 4, 2023
8:30 a.m.

Zoom:
CPHS August 4, 2023 Full Committee Meeting
Meeting ID: 160 097 8983
Passcode: 789976

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

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Meeting ID: 160 097 8983

CDII
John Ohanian, Director
Nick Picinich, Deputy Director

MINUTES

Committee Members Present In Person:
Juan Ruiz, MD, DrPH, Chair
Carrie M. Kurtural, JD
Catherine Hess, PhD
Laura Lund, MA
John Schaeuble, PhD, MS

Committee Members Present Remotely:
Larry Dickey, MD, MPH, Vice Chair
Alicia Bazzano, MD, PhD
Philip Palacio, EdD, MS

CPHS Staff Present:
Lucila Martinez
Sussan Atifeh
Karima Muhammad

Center for Data Insights and Innovation
Sheryl McCarthy
Ruben Mejia

Also, Present (All via ZoomGov) Principal Investigators and Associate Investigators
Susan Sabatier, CDPH/WIC
Chelsea Hart-Connor, CDPH/WIC
Tim Mulcahy, Westat
Christine Borger, Westat
Bibi Gollapudi, Westat
Chandni Parikh, UCD
Rachel Ni, UCD
Sally Ozonoff, UCD
Joe Zickafoose, Mathematica
Matt Niedzwiecki, Mathematica
Dana Pederson, Mathematica
Kendall Darfler, UCLA
Darren Urada, UCLA
Eileen Rillamas-Sun, Fred Hutchinson Cancer Center
Jenny Whitten-Brannon, Fred Hutchinson Cancer Center
Lia Fernald, UCB
Rita Hamad, Harvard University
Nicole Fernandez-Vina, UCB
Zoe Varner, UCB
Wendi Gosliner, UCANR
Shannon Coulter, SDCOE
Jonathan Isler, CDE

A. Welcome

a. Chair Updates

Dr. Ruiz requested Ms. Lund to explain about some problems with long-term studies that have requested vital records from the California Department of Public Health (CDPH), Vital Statistics Advisory Committee (VSAC).

Ms. Lund mentioned, “The problem with these long-term projects is that the Principal Investigator (PI) and the research staff of the originally approved study might have been changed without transferring the information to the new PI and new study personnel in a correct way which can cause reporting some adverse events for these long-term projects.”

Ms. Lund also said that Dr. Dickey and herself approached CDPH/VSAC and per an agreement with CDPH, any research study using birth and death data must submit a new research application to CDPH through the VSAC process every five years for the duration of the study and CPHS’ continuing approval for research projects of greater than five years duration will be contingent on receiving a new VSAC approval letter for the project every five years.

Ms. Lund and Dr. Dickey have developed language to add to the previously posted document on the CPHS website named as “CPHS Statement for Birth and Death Data”. The added language will alert researchers that if they are requesting VSAC data for longer than five years, they must return to VSAC every five years for review and approval, and that the next CPHS approval of the “Continuing Review” application for that project will be contingent on a new VSAC approval letter every five years.

B. Administrator Updates

Lucila Martinez, the CPHS Acting Administrator explained about the importance of timelines when requesting feedbacks from the CPHS Committee members. This will assist staff to ensure the deadlines are met for preparing and posting documents.

C. Review and Approval of Meeting Minutes

a. April 7, 2023.

It was moved by Ms. Lund and seconded by Ms. Kurtural to approve the April 7, 2023, Meeting minutes.

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

b. June 2, 2023.

It was moved by Dr. Hess and seconded by Ms. Kurtural to approve the June 2, 2023, Meeting minutes.

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

D. Projects with Reported Adverse Events and/or Deviations

1. Project # 2020-132 (Ruiz)
   Title: Online Screening for Autism in the Community
   PI: Chandni Parikh, PhD
   Co-PI:
   Board Decision: Approved

This study tests new methods of screening for autism in a large community-based sample via a completely online system.
The adverse event occurred on November 25, 2022, when an email was sent to the wrong family. Given the online nature and the large scope of the study, once the participants are enrolled, email is the primary method for all study-related communications. The research team sends a reminder email to complete the online questionnaires. In this case a participant's first name and study-specific username were incorrectly emailed to another participant.
This mistake occurred because two participants had parents with the same first name and very similar email addresses. The breach included no other confidential information, and the incorrect recipient of the email did not have any of their information disclosed.
This was an isolated incident involving a single participant, and the only information from the vital records data files was the child's first name.
The error was immediately detected by the staff member, who notified her supervisor within minutes, and because the incident occurred over a long holiday weekend, it was immediately reported to the University of California, Davis (UCD) IRB on the next working day, on November 28, 2022. The UCD' IRB reviewed and acknowledged the incident, and a corrective action plan was immediately implemented. The corrective actions are regularly reviewed by the entire research team to verify its implementation. Researchers did not report it to CPHS until the time of submitting the Continuing Review application when they were notified by the primary reviewer of the project to submit the adverse event to CPHS. Immediately after researchers recognized that this adverse event should have been reported to CPHS, they submitted the report.
Researchers sent an email to the affected party, notifying them of the breach, acknowledging responsibility and providing details of the incident and offering the family the opportunity to withdraw from the study. The family selected not to withdraw from the study.
Ms. Lund then recommended, "Since this involves an unauthorized sharing of the California Department of Public Health (CDPH) data, then CDPH should be informed."

Motion:
It was moved by Dr. Dickey and seconded by Ms. Lund to accept this report and to request the researchers to notify the California Department of Public Health (CDPH) regarding the breach.

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

Total=8 In Favor-5, Opposed-0, Abstained-3

2. 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: Tabled

This study includes a telephone interview with the child's caregiver and the collection of the study child's height/weight measurements around the ninth birthday. Westat used the MOVEit Secure File Transfer Protocol (SFTP) system made by the external vendor Progress Software to operate a website for the purposes of securely exchanging files. On May 30, 2023, Westat discovered a data security incident involving the Progress MOVEit Secure File Transfer Protocol (SFTP) system. On Sunday, May 28, 2023, a hacker used a previously unknown software flaw in Progress Software's system to bypass multiple security controls and download files from Westat's SFTP server. The unauthorized download included two measurement records and two interview recordings with potentially identifying information for a total of four individual caregiver/child dyads enrolled into the study from WIC clinics in California.

In the two measurement records, the potentially identifying information includes the child's Date of Birth (DOB) and the caregiver's name, in addition to the child's height and weight.

In the two interview files, the potentially identifying information includes the child's first name and the caregiver's name. In one of the two interview files, the caregiver's state of residence is also mentioned.

Upon detecting the threat, Westat immediately took steps to ensure the security of the system, and with the assistance of third-party forensic specialists, investigated to determine the nature and scope of the activity.
The investigation is complete, and encrypted copies have been provided to the committee members.
Researchers also notified Federal law enforcement authorities of the incident and continue to cooperate with their investigation.
Westat has decided to use the Globalscape SFTP, a secure system with a solid track record. The system is currently used by many Federal agencies and meets the functional needs of the moving system.
Researchers have implemented a new data retention policy in place that stipulates that all files uploaded to this new server will be automatically deleted after being downloaded. If files are not downloaded in five days they are automatically deleted for additional security. All sensitive files, regardless of where they are stored, will be encrypted.

It is important to send Notification of breach to the affected participants.

The CPHS committee members could not open the encrypted reports. The reports should be provided to the committee members in an unencrypted format so they can access them, or the agency should provide the members with a software needed to open the files. There was not any personal information or anything regarding the participants who had been breached in the encrypted reports and the reports are mainly explaining what occurred.

Motion:
It was moved by Dr. Dickey and seconded by Dr. Schaeuble to request researchers to send unencrypted copy of technical reports to CDPH Information Security Officer (ISO) and to CPHS. Also, notification of the breach should be sent to affected subjects. Before sending notification of breach to the affected subjects, a subcommittee consisting of Dr. Dickey, Dr. Schaeuble, and Ms. Kurtural will review notification for compliance with IPA. CPHS will reconsider this adverse event at the next meeting.

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

Total=8 In Favor-5, Opposed-0, Abstained-3

E. New Projects – Full Committee Review Required

1.	Project #	2023-119 (Hess)
	Title:	California Hub and Spoke System Provider and Administrator Surveys
	PI:	Darren Urada, PhD
	Co-PI:	Kendall Darfler, MS
	Board Decision:	Approved Pending Conditions - Designee Review

The UCLA Integrated Substance Abuse Programs (ISAP) is providing project evaluation services to the California Department of Health Care Services (DHCS) on the state-funded California Medications for Addiction Treatment (MAT) Expansion: Hub and Spoke System (HSS) Project. This project which is titled as "California Hub and Spoke System (HSS) Provider and Administrator Surveys" is a component of the larger program evaluation to conduct a survey with MAT prescribers, program administrators, and MAT team members who include supportive clinicians, such as nurses, and behavioral health specialists for the California Hub and Spoke program.
The purpose of these surveys is to inform the program evaluation to gather providers' and administrators' perspectives on how the implementation of the Hub and Spoke program is going, barriers and facilitators to prescribing MAT, knowledge and attitudes about service, delivery practices, needs for training and technical assistance, and plans and practices to address health equity.
Researchers requested to add demographics and a waiver of informed consent because signature may be identifiable.
The demographic information is fully voluntary, and researchers have made that clear in the information sheet.
Researchers have already addressed most of the comments left by Dr. Hess in the application.
Dr. Hess mentioned, "The surveys include demographic information such as age, gender identity, sexual orientation, and race/ethnicity and it is concerning because this is potentially identifiable information, especially when coupled with the measures on the participant's specific Hub and Spoke site location."
Researchers plan to collect demographic data, but they will not report it at the site level, and they will report it in aggregate to get a better sense of how the representatives, providers, and administrators who are working under this program are of the patient population that they're serving, and it is just aimed at gathering representativeness in aggregate.
Researchers will reconsider whether the question about sexual identity is necessary.
Researchers were recommended by Ms. Lund to assign a unique identifier for each site, so that when the detailed demographic information is stored it's only with an anonymized site identifier and when researchers plan to analyze by site, that file will not contain the detailed demographic information. This encrypted data leaves no linking potentials and identifying that detailed data.
Dr. Schaeuble recommended researchers to send the information sheet with recruitment email to people so that they can see it early and not having to wait until they are actually beginning the survey.
The University of California, Los Angeles (UCLA) IRB has deemed this project is not research, because the purpose is program evaluation.

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

1. Create a unique identifier for each site so that there is no link between the demographic information and site and clarifying about it in the CPHS project application.
2. Include the information sheet in the recruitment email.
3. Clarify in the information sheet that the CPHS contact information is only for responding any questions relating to the rights of participants, and not for responding questions relating to the project.
4. Seek authorization agreement between UCLA IRB and CPHS.

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

Total=8 In Favor-5, Opposed-0, Abstained-3

2. Project # 2023-120 (Palacio)
Title: Using a SMART Design to Evaluate Remotely Delivered, Culturally Tailored Weight Loss Interventions Among Latina Breast Cancer Survivors
PI: Heather Greenlee, ND, PhD
Board Decision: Approved Pending Conditions - Designee Review

This study is a RO1-funded study that is focusing on the Hispanic Latina breast cancer survivors living in Washington and California, who are obese. Researchers plan to do a sequential multiple assignment randomized trial (SMART) testing 12 months adaptive culturally tailored weight loss interventions in a geographically diverse group of Latina breast cancer survivors. The goal of this program is to achieve 7% weight loss.
Researchers will include all recruitment materials that will be sent to all participants from the states of Washington and California. Researchers will include a copy of the Bill of Rights in the consent form. The intervention will be conducted in both English and Spanish. Researchers will submit an amendment for the review and approval of recruitment materials translated in Spanish.
The consent form does not describe the personal information that researchers requested from the cancer registry and lacks the level of detail needed to inform the participant that researchers will be collecting this level of information. Researchers will modify the consent form.
There is a question in the “HIPAA Authorization” form issued by the Fred Hutch Institutional Review Board (IRB) to request permission for capturing participants’ personal information including any diagnosis or treatment of HIV/AIDS, and mental illness. Researchers were notified by Dr. Palacio that this question is not appropriate for the study and will work to change the language and resubmit the “HIPAA Authorization” form for approval.
Dr. Schaeuble mentioned that If changing the HIPAA form was difficult, then researchers should ensure that the HIPAA form included a “No” box for information about HIV/AIDS, and mental illness and the “No” box was checked.
Participants should have online access to the Internet, and a computer or a smartphone as part of their eligibility criteria in order to participate in the intervention. The intervention is a remotely delivered intervention.
The more serious risks to participants associated with physical activity like falling down, heart problems, and possibly death have not been described in the protocol or the consent form and it is logical to acknowledge these risks in the consent form.
Dr. Dickey mentioned, “As long as researchers acknowledge the more serious risks in the consent form, they don't have to report it as an unanticipated problem to CPHS whenever it actually happens because it's something that researchers have already anticipated it might happen.”
The educators that are delivering the live interventions are very well-trained and they will be able to monitor the participants.
Participants will be asked to do a finger stick, but it has not been described in the consent form.

The California Cancer Registry (CCR) Requires researchers to inform the participants’ doctors of record that they are being involved in a research study. The participants’ current doctors could be the doctors of record, but they also might not be. If a participant’s doctor on record is not the current primary doctor then the current doctor’s approval is needed for consent. Researchers were requested to gather information about the participants’ current doctors at the time of recruitment.
Researchers will be contacting the participants’ doctors and they will clarify it in the consent form that the participants’ doctors have been informed about this project and have already approved their participation in this study.

The use of the Fitbit data should be described in the consent form. Researchers should ensure that the consent form fully describes the information that Fitbit potentially collects. Researchers should obtain and attach a copy of the agreement signed by the users that allows them to opt out on any information that is being collected from the Fitbit data.

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

1. The "Cover Letter", "FAQ", and "Recruitment Letter" should be modified specifically for the state of California.
2. The Medical Bill of Rights will be provided along with the consent form.
3. After the approval of the study, an amendment application should be submitted for the review and approval of the documents translated on Spanish.
4. The consent form should be modified to discuss the risks associated with the use of Fitbit as well as the protections that will be put in place to limit the data collection.
5. The language of the "HIPAA Authorization" form for the question that requests permission for capturing participants' personal information including any diagnosis or treatment of HIV/AIDS, and mental illness, either should be edited or the "No" box should be checked.
6. Researchers should find similar studies and use the same language on the consent form to include the more serious risks that were not mentioned in the consent form including "injury", "falling down", etc.
7. The approval from the participants' current doctors is needed for the enrollment in the study.
8. The consent form should include information regarding data obtained from the Cancer Registry.
9. The Consent form should include information regarding finger sticks.

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

Total=8 In Favor-5, Opposed-0, Abstained-3

3.	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

In late 2022 California Health and Human Services Agency (CalHHS) contracted with Mathematica and a couple partner organizations to evaluate the California Children and Youth Behavioral Health Initiative (CYBHI) which was funded by the Legislature in 2021.
This project application covers two initial pieces of the evaluation including “Initial qualitative key informant interviews at the State level” and “Analyses of de-identified publicly available secondary data sources.”
The key informant interviews are sixty-minute semi-structure discussions with state level respondents including policymakers, CalHHS agency staff, non-governmental education and other child-serving organization staff, and state-level managed care plan representatives. The interviews focus on their knowledge and experience with the CYBHI, and they are planned to be conducted in fall of 2023. The interviews will be confidential, and the final reports will include aggregated and anonymized information.
For the second piece of the application related to the secondary data analyses, there will be using data sources primarily without any HIPAA identifiers. They are a wide range of data sources that include national level and state level surveys with publicly available data, but they do also include a couple of exceptions that are three surveys from the California Department of Education (CDE) that include more specific school identifiers, even though individual responses are de-identified.
For the school surveys, there's no personally identifying information. and researchers will only report means or other statistics from these data when cell size is 11 or greater and the geographic unit (county or region) includes at least 20,000 people.
Researchers will be looking at some professional Licensure data that includes personally identifiable information which is publicly available through the Licensing Board websites.
Researchers plan to add other secondary data sources and a survey of caregivers and youth in a later amendment.
The list of main topics is still missing in the calendar invitation email and researchers were requested to include the missing information and upload the document.
Dr. Schaeuble requested that researchers to replace the last 2 paragraphs in the audio recording section of the consent form with "We will not use your last name in the interview. May we use your first name, or would you prefer that we substitute a pseudonym to preserve your privacy?"
Dr. Schaeuble mentioned that for consistency with the respective headings, it would be better to rearrange the location of some sentences in the consent form and under “Your participation is voluntary" it could be stated that “Your participation in this evaluation is private and voluntary. You have the right to withdraw your consent or stop participating at any time. You also have the right to refuse to answer any of our questions during the interview. The interview will last about 60 minutes."
Also, under “Measures to ensure confidentiality" section it could be stated that “I want to emphasize that there are no right or wrong answers. We also do not expect you to be knowledgeable about every topic—if we ask you about something you are unfamiliar with, just let us know and we will move on to another topic. You may also choose not to answer any of the questions. We are simply interested in hearing your opinions and experiences with CYBHI. The

researchers involved in the study will protect the privacy of your responses, even if you criticize CYBHI or other groups."
The consent form should say "his" instead of "her" to point the email address for David Wittenburg.
The reading level of the consent form is 11.4, which is considered difficult to read. Researchers were requested to consider revisions that would reduce the reading level to grade 9.
The CDE Surveys that will be used include “The California Healthy Kids Survey”, “The California School Parent Survey” and “The California School Staff Survey.”
Researchers do not have any plan for analyzing the district level or school level data at this time.

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

1. Include the list of interview topics in the calendar invitation email.
2. Revise the audio recording section of the consent form as indicated in comments to PI.
3. Rearrange sentences under “Your participation is voluntary” and “Measures to ensure confidentiality" sections of the consent form as stated in the comments to the PI.
4. Change pronoun for the email address for David Wittenburg.
5. Reduce reading level of the consent form to a goal of 8th grade or as close as possible.

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

Total=8 In Favor-5, Opposed-0, Abstained-3

4. Project # 2023-128 (Lund)
Title: Targeting Access and Knowledge of EITC Utilization and Policies (TAKE-UP) II
PI: Lia Fernald, PhD
Co-PI: Rita Hamad, MD, PhD
Wendi Gosliner, DrPH, RD
Board Decision: Approved

This study is about the Earned Income Tax Credit (EITC), which is the largest poverty alleviation program for families with children in the United States, and it's structured as a credit through the tax system.
Twenty percent of California Women, Infants, and Children (WIC) families who are eligible to receive the EITC and The California Earned Income Tax Credit (CalEITC) are not getting it. Improving the take up of EITC is a priority for the California Department of Public Health (CDPH), as well as for the WIC program, and researchers are working in partnership with WIC on the study which aims to capture WIC participants' perceptions about the EITC and potential future interventions that could improve the take up of EITC.
Researchers have planned to conduct a self-administered survey of California WIC participants to understand whether there might be differences by a language, racial, or ethnic subgroups. The goal of the study is to inform WIC and the broader scientific and practice community about potentially effective ways to increase the take up of EITC. The EITC has been found to be a benefit associated with improved health, particularly for pregnant women and young children.
Researchers clarified that the survey results will be described in both peer-reviewed journals and a report to WIC.
Researchers have omitted the screener question requesting the participant's name because there was no need for personally identifying information at that level. For the follow up purposes, the researchers have changed the request in the survey to "Please provide your name at this time if you are willing to be contacted for future studies."
All data analysis will be done at the University of California, Berkeley (UCB) and even though there are multiple institutional affiliations, the security of the data being obtained, stored, and/or used for this research project is supported by UCB where the data will be accessed and analyzed.
Researchers edited the consent form to give the participants the name of an actual person that they can contact instead of just an email and phone number.
Researchers clarified that survey data will not be shared with the California Department of Public Health (CDPH) and CDPH only will receive reports and aggregated data.

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

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

Total=8 In Favor-5, Opposed-0, Abstained-3

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

This project 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 is online modules that teachers will be engaged in. Teachers take a pre-assessment test, complete the module that teaches them about reading strategies, and then they take a post test. The data will be gathered from the pre and post-test results from the learning management system where all these modules are housed and will be linked to the student achievement records that researchers requested from CDE.
The program administrators of the RII grant program will capture additional data from the participants, by surveying and interviewing them. The data gathered from the surveys and interviews also will be linked to the student achievement records from CDE.
Researchers will include note in the application to clarify that "PL" is an acronym of "Professional Learning."
Researchers have planned to conduct the interviews via Zoom by audio recording. In the "Recording" section of the application, the answer should be changed from "No" to "Yes."
Most teachers don't know the statewide teacher identification number. Researchers have to figure out how to connect students to their teachers, so that they can determine what their achievement scores are on third grade reading assessments.
Most kids have local student ID numbers not a Statewide Student Identifier (SSID). The most critical piece is that researchers can link the child to the teacher. In some places it can be done by using the local student ID number but in some situations it should be done through other means because most teachers don use the Statewide Student Identifier (SSID).
There's a memorandum of understanding that will be sent to the participating teachers to gain their consent to participate in the study. Researchers have not planned for gaining consent from the students.
Committee members are concerned about the amount of extremely personal and sensitive information that researchers are gathering from the Department of Education (CDE) database. If these students are being subjected to an experimental intervention, the parents should be made aware, and should have the opportunity to opt out.
The learning modules are open to all teachers in the State of California with potential impact of all students in the State of California. The other evaluation group that has been contracted by the State of California is the American Institute for Research (AIR). There is a discrete number of teachers with discrete number of students who are participating in this particular evaluation, and it is important to make the parents of those students aware that their children's data is going to be used in an evaluation and give them the opportunity to opt out. Researchers will prepare a letter to inform parents and attach it to the application. The smaller group of teachers will be involved in the Zoom video interview and a larger group of teachers will be involved in taking the survey. Researchers will clarify about it in the "Population Description" section of the application.
Researchers were requested to explain about the possible risks to the participants including but not limited to loss of confidentiality, risk of discomfort when answering the questions, and risk of loss of data privacy in the "Risk Description" section of the application.
Researchers were requested to explain about the less risky methods including the using of anonymous surveys, not using recording, using aggregated or historical data regarding student performance, etc. and describe why the less risky methods are not being chosen in this study.

Researchers are recommended to include in the application that professional learning would be beneficial to the participants.
There are some HIPAA identifiers in the requested data and should be listed in the “HIPAA Identifiers” section of the application even if they will be hashed.
Researchers should describe in the “Training Procedures” section of the application whether PI and other project’s staff have had training on human subjects like “CITI” training, etc., and whether they have signed confidentiality statements regarding data use and privacy.
Researchers should specify in the application which staff have access to Personally Identifiable Data (PID) and add them to the application. Researchers were requested to clarify in the application that cell sizes less than 15 will be masked.
Researchers should revise the application to clarify that data is limited to those who need to know for implementing or evaluation, whether the respondents could be matched using their unique identifiers instead of their names, and why the respondents’ emails are needed for the linkage. Researchers should clarify in the application what data will be destroyed, retained, be de-identified, or be returned. They also need to clarify how it can be done and when.
All comments regarding the data security should be addressed by researchers in the application. Researchers should clarify in the application about the availability of the opt-out question for the teachers as well as parents. Consent form should explain the linkage of all data sets and how they are being used. The data is aggregated to the school level and shared with the project administrators and is not shared back to the school. Researchers will not report any individual level data for this project and will suppress cell sizes of less than 30 in any evaluation reports. There will also be reporting at the district level which would allow to aggregate across schools for places that have really small cell sizes. If it cannot be done at the school level, then it would be done at the district level, and if it cannot be done at the district level, it would be done at the project level. It is not clear yet how many teachers are going to participate in each site.
Dr. Dickey mentioned, “The HIPAA identifiers, are only designed for health data and the identifiers in this project are not health data and in the future this issue should be addressed in the application in IRBManager.”
Dr. Bazzano mentioned, “The HIPAA and FERPA identifiers are very similar, and this is an education study, not a health study and if the FERPA identifiers be included in a specific section of the application it would be helpful.”
Researchers recommended that instructions specifically around FERPA identifiers for education-specific projects to be posted on the CPHS website since it would be very helpful for the California Department of Education (CDE) and the research partners that they have worked with. Lucila Martinez, the CPHS Administrator mentioned, “ We can plan for a meeting to discuss this recommendation in more details and also we are willing to work with the CPHS website coordinator to put a link for the requested information on the CPHS website.”

Motion:
It was moved by Dr. Bazzano and seconded by Ms. Lund to table this project until the next meeting which will be held on October 6th, 2023, and Dr. Bazzano will work with the PI to make the required changes.

Approved: Ms. Lund, Dr. Hess, Ms. Kurtural, Dr. Schaeuble, Dr. Ruiz.
Abstain: Dr. Dickey, Dr. Palacio, Dr. Bazzano.
Oppose: None.
Absent: Dr. Dinis.

Total=8 In Favor-5, Opposed-0, Abstained-3

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 (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 (16)

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 (20)

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 (67)

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 (29)

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

None.

M. Exemption/Not Research Approvals

Total Project Count (14)

N. Final Reports

Total Project Count (9)

O. Public Comments

None.

P. Next Meeting

The next CPHS meeting has been scheduled for Friday, October 6, 2023.

Q. Adjournment

This meeting was adjourned at 12:02 PM.