State of California—Health and Human Services Agency

Committee for the Protection of Human Subjects

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

GAVIN NEWSOM
Governor

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

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

Alternate Member
Millard Murphy, JD

Administrator
Lucila Martinez

Friday, June 2, 2023
8:30 a.m.

Zoom:
CPHS June Full Committee Meeting

Meeting ID: 160 401 6242
Passcode: 141717

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CDII
John Ohanian, Director

MINUTES

Committee Members Present:
Juan Ruiz, MD, DrPH, Chair
Larry Dickey, MD, MPH, Vice Chair
Alicia Bazzano, MD, PhD
Carrie M. Kurtural, JD
Catherine Hess, PhD
Laura Lund, MA
Maria Dinis, PhD, MSW
Philip Palacio, EdD, MS
John Schaeuble, PhD, 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
Jesse Rothstein, UCB
Nick Gebbia, UCB
Evan White, UCB
Jennifer Hogg, UCB
Miriam Komaromy, BU
Mallika Bhandarkar, RAND
Lorretta Erhunmwunsee, COH
Aamna Akhtar, COH

Richard Curley, COH
Nicole Herrera, COH
Yi Xiao, COH
Mara Decker, UCSF
Sarah Bottjer, USC
Martin Nunez Rivera, USC
Meera Adya, SDSU
Leslie Baker, DOR
Carol Asch, DOR
Mark Ehrlichman, DOR
Nadereh Pourat, UCLA
Brenna O'Masta, UCLA
Roy Ahn, NORC
Mithuna Srinivasan, NORC
Shena Popat, NORC
Albert Farias, USC
Ann Hamilton, USC
Denise Modjeski, U

A. Welcome

a. Chair Updates

None.

B. CPHS Membership Nominees

a. Allen Azizian, PhD-Department of State Hospitals

Dr. Azizian has a PhD in psychology and has been with the California Department of State Hospitals (DHS). Dr. Azizian is an associate professor at the Department of Criminology, Forensic Behavioral Sciences, at the California State University, Fresno.

Motion: It was moved by Ms. Kurtural and seconded by Dr. Dickey to appoint Dr. Allen Azizian as a board member to the Committee for the Protection of Human Subjects (CPHS).

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

b. Maria Ventura, PhD-Department of State Hospitals

Dr. Ventura has a PhD in developmental psychology and recently is working with the California Department of State Hospitals (DSH). Dr. Ventura has worked with MIND Institute. Dr. Ventura has completed her post-doctoral training in geriatrics, epidemiology and biostatistics at the University of California, San Francisco (UCSF) and she is committed to the ethical practice of research.

Motion: It was moved by Ms. Kurtural and seconded by Dr. Dickey to appoint Dr. Maria Ventura as a board member to the Committee for the protection of Human subjects (CPHS).

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

c. Jonni Johnson, PhD-California Department of Public Health

Dr. Johnson has a PhD in developmental psychology from the University of California, Davis (UCD) and has been with the California Department of Public Health (CDPH). Dr. Johnson has several expertise in the area of data analysis and vital records. Her dissertation has focused on memory development in youth, with and without autism, and assessing the limitations of existing forensic interview protocols for youth with disabilities.

Motion: It was moved by Ms. Kurtural and seconded by Dr. Dickey to appoint Dr. Jonni Johnson as a board member to the Committee for the Protection of Human Subjects (CPHS).

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

C. Los Angeles County Department of Public Health (LACDPH) Updates on Los Angeles Mom and Baby (LAMB) Project Adverse Event

Researchers at the Los Angeles County Department of Public Health (LACDPH) have continued to make outreach to the remaining two researchers who had access to the data, but they have not been able to reach them. The researcher indicated in their last report regarding the adverse event on this protocol that they had contacted the two researchers' institutions by sending emails and a letter to inform them of the urgency of the issue, and the need to destroy the information. The other researchers have destroyed data in accordance with protocols without sharing it further, and their projects are closed. The Maternal, Child, and Adolescent Health Division (MCAHD) at the Los Angeles County Department of Public Health (LACDPH) stated they had committed to making some changes to their website to communicate publicly that the LAMB project data is not available to external researchers, and they should obtain the vital record data through appropriate channels.

The MCAHD is ensuring that any vital reference data have been recommunicated and reinforced, as well as the staff who use vital references provide proof of completion and maintenance of trainings for use of this information.

Also, the Office of Health Assessment and Epidemiology at the LACDPH has required an internal Data Use Agreement with the staff within the department who use vital records can be monitored. Researchers clarified that they plan to close the LAMB project, and to look into alternate data sources to respond to some of the questions of the project. The proposed closure date is December 31, 2023. In addition, the researchers should clarify in their next report whether they would be using or accessing the data further internally after this date.

Regarding the two missing contacts, Dr. Bazzano recommended researchers to search particular online sources to the researchers, such as Google Scholar and PubMed.

Dr. Bazzano mentioned, "The institutions of the two researchers have more responsibilities even if the two researchers are no longer there and the institutions are responsible for trying

to contact their ex-employees."

Dr. Bazzano also recommended that LACDPH to reach out to the two researchers' departments, their departments' chairs, and the risk management teams from their institutions. She further stated to request contact information for the two researchers but also to inform them about their responsibilities for destroying the data if it is still in their possession.

Motion: It was moved by Ms. Lund and seconded by Dr. Dickey to accept the corrective actions to remedy the event so far and request the additional following activities from LACDPH in regard to following up on the two researchers who have not yet been reached.

1. **LACDPH should contact the department chair and the Risk Management Office at the two researchers' institutions to find out if they have contact information for the researchers. Also, that are to inform them of their responsibilities to destroy or return the data if it is remains in their possession.**
1. **LACDPH should search online sources that are specific to the research communities, such as Google Scholar and PubMed, to determine whether they are to find any information about the two missing contacts.**

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

D. Administrator Updates

Lucila Martinez, the CPHS Acting Administrator announced that Dr. Ruiz would leave the meeting at 10:45 am, and then Dr. Dickey would be the lead for the remaining of the meeting.

E. Review and Approval of Meeting Minutes

a. April 7, 2023

Dr. Schaeuble requested to postpone the approval of the April 7, 2023, meeting minutes to the August 4th, 2023, meeting.

F. Projects with Reported Adverse Events and/or Deviations

1. Project # 12-08-0658 (Ruiz)
   Title: Personal Responsibility and Education Program (PREP) Evaluation
   PI: Celeste Doerr, PhD
   Co-PI: Mara Decker, DrPH
   Board Decision: Approved

Discussion:

A staff member at one of the local agencies administered the baseline surveys, and then found out that two of the people who received the surveys had parents who had opted out and they should not have received that survey. The agency notified researchers immediately. Researchers followed up with the agency and provided training on responsibility and processes for tracking survey consent forms prior to survey administration.

Motion: It was moved by Dr. Dickey and seconded by Dr. Schaeuble to accept this event and the researchers' corrective actions.

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

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

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

Discussion:

This project is a randomized clinical trial testing the impact of the collaborative care model on the ability of providers in a primary care setting to provide care for patients who have opioid use disorder along with co-occurring mental health disorders, depression, and PTSD. The project is being conducted in multiple primary care settings in New Mexico and in California.
The incident involved unintended disclosure of information about study participants. A care coordinator in a primary care clinic was involved in identifying potential candidates to enroll in the study, and she inadvertently sent an email to several members of the study team that included a patient's name that was not enrolled in the study at that time. This was identified promptly. A request was sent to delete all copies of the email. Staff were advised that email is not a secure way of sending protected health information.
Researchers contacted all individuals who had received the email and the involved IT departments to request to delete the email off of the server in addition to their personal computers. Researchers clarified that there were not any adverse consequences from this that they were aware of.

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

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

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

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

Discussion:

A patient sent an email directly to one of the data analysts that included the patient's own name. The data analyst's email address mistakenly had been included on the automatic form during the testing phase in REDCap (Research Electronic Data Capture). The analyst was not authorized to see the personal information of the participants. The problem was immediately detected and addressed by removing the link to additional emails to prevent reoccurring. The only people who saw the name of the potential participant were study personnel, and the email was not sent to anyone else. Researchers clarified that everyone in the study has been trained in data confidentiality and protection of personal health information and the data analyst did not disclose the information to anyone after receiving it. Also, the data analyst has been counseled.

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

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

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

4. Project # 2022-004 (Lund)
   Title: The Impact of Racism-Related Socio-Environmental Factors on African American Non-Small Cell Lung Cancer (NSCLC) Mutational Signatures
   PI: Loretta Erhunmwunsee, MD
   Co-PI:
   Board Decision: Approved

Discussion:

A deviation regarding the Medical Release Form was discovered on May 3rd, 2023. This deviation occurred because study staff made edits to the IRB approved Medical Release Form and sent the edited form to participants without obtaining IRB approval. The edited forms were sent to twenty-four individuals before they were submitted to IRB for approval. Ten of the 24 participants completed the unapproved medical release. The City of Hope IRB reviewed and accepted the adverse event as informational and approved the researchers' preventive action plan and corrective actions plan.

The correct version of the medical release form was mailed out to all 24 subjects affected by this deviation on May 3rd, 2023. Researchers gave three weeks to account for the time it will take for patients to receive the medical release form in the mail and send it back to the study team. Researchers started the corrective action plan by sending the approved medical release form to all twenty-four participants in part 2. Ten of the twenty-four participants had filled out the edited, unapproved medical release form. Researchers contacted the ten participants to fill out the currently approved version and to notify them of an updated medical release form that would be incoming shortly. Of the ten participants, the majority decided to hold off on completing the medical release form till the updated version is sent.

An amendment was also submitted to CPHS and City of Hope IRB to approve the updated version of the medical release form. They received CPHS approval for the edited version but did not send the form out to participants because they were notified of a medical release form that is more appropriate for the study. Upon confirming, the updated medical release form will be submitted to CPHS and City of Hope IRB for approval and then the most current approved form will be sent out to all participants.

To ensure this does not occur in the future, all study staff reviewed the IRIS training modules and relevant parts of the City of Hope (COH) Human Research Protections Program Standard Operating Procedure Manual before May 9th, 2023. By May 12th, 2023, relevant documents to this deviation from the Clinical Research Protections website under Research Education, Training, and Guidance Documents were reviewed by study staff. The goal of reviewing these documents is to ensure that study staff better understand IRIS, the amendment process, and rules and regulations outlined by the IRB for patient safety and best practices.

Additionally, for the next three months, all documentation for study participants enrolled in the study will be reviewed by the project manager and the department of surgery senior manager of the clinical research program. For the on-boarding and future study staff, there will be a two-month period of managers reviewing all completed patient-facing documents to ensure up-to-date and correct forms are being used for study activities. Future study staff will also be required to read the Standard Operating Procedure manual and partake in IRIS training prior to beginning the two-month probationary period. The preventive action plan is on-going. Training

was completed on May 12th, 2023. Each document will be reviewed by managers prior to their upload to the drive. For all currently enrolled participants with the incorrect form, the project manager will review all documents received before they are uploaded to the drive for additional use.

Ms. Lund clarified that the researchers had already addressed all the comments in the application properly.

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

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

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

5. Project # 2022-004 (Lund)
   Title: The Impact of Racism-Related Socio-Environmental Factors on African American Non-Small Cell Lung Cancer (NSCLC) Mutational Signatures
   PI: Loretta Erhunmwunsee, MD
   Co-PI:
   Board Decision: Approved

Discussion:

This was an administrative deviation that have been regarding the informed consent, the information sheet, and the documentation of consent. It was discovered on April twenty eighth at City of Hope. There are two places where documents are available. One version is on IRIS, and the other is the OnCore Version. The participants were sent the version of the informed consent and the consent information sheets from IRIS. IRIS documents have a visible watermark on all pages of the consent documents and do not include the attestation page. All twenty-five participants in this study were sent the incorrect version from IRIS. Researchers reported the event to City of Hope and CPHS on May 3rd, within 5 business days. There were no conditions set by the City of Hope IRB and the preventive action plan and corrective actions were accepted. The correct version was sent to all participants, with a letter explaining why additional signatures are needed. The OnCore consent information sheet for part 1, and the OnCore informed consent and medical release form for part 2 were sent to all subjects. For part 2, participants will be asked to re-sign the consent forms and return them to the study team in three weeks.

They tried to contact the ten participants who had completed the consent process to initiate the re-consent process. Two patients decided to sign the consent form and send it back, 2 patients asked to hold off on the consent process until the updated medical release form was available, and researchers were unable to contact the remaining 6 patients. Researchers might not be able to contact one participant and they requested that the study team to proceed with the water-marked version of the informed consent form to obtain their tumor samples since the forms are current with correct information.

To ensure this does not occur in the future, all study staff have been re-trained on navigating OnCore as of May 4th, 2023. The corrective action was the live training performed by a COH OnCore specialist that covered various topics, including proper navigation of study documents on OnCore.

All IRIS training modules and relevant parts of the COH Human Research Protection Program (HRPP) Standard Operating Procedure Manual were reviewed on May 9th, 2023. The goal with these trainings was to better understand what the systems offer, and which documents are appropriate to use while conducting different parts of the study.

Additionally, for the next three months, all documentation for study participants enrolled in the study will be reviewed by the program manager and the Department of Surgery senior manager of the clinical research program. For the on-boarding and future study staff, there will be a two-month period of managers reviewing all completed consenting documents to ensure up-to-date and correct forms are being used for the consenting process. Future study staff will also be required to go through the OnCore training, reviewing of the Standard Operating Procedure manual, and IRIS training prior to the beginning of the two-month probationary period.
The preventive action plan is on-going. For all currently enrolled participants with the incorrect

forms, the manager will review all documents received before they are uploaded to the drive for additional use.

Ms. Lund mentioned, “This adverse event happened due to lack of appropriate training and corrective action plan addresses that issue properly. It is a bureaucratic technical error as opposed to any error that might have led to a lack of information or misinformation for subjects. Researcher had addressed all the comments and no harm was done to participants.”

Motion: It was moved by Ms. Lund and seconded by Dr. Schaeuble to accept this event as submitted and to allow the researchers to use the watermarked version of the consent form for the one person that they have difficulty to reach.

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

Total=8 In Favor-7, Opposed-0, Abstained-1

G. New Projects – Full Committee Review Required

1. Project # 2023-078 (Schaeuble)
   Title: Multilevel Influences That Contribute to Racial/Ethnic Disparities in Receipt of Guideline Concordant Treatment for Early-Stage Non-Small Cell Lung Carcinoma (NSCLC)
   PI: Albert Farias, PhD, MPH
   Co-PI: Ann Hamilton, PhD
   Lihua Liu, PhD
   Myles Cockburn, PhD
   Board Decision: Approved Pending Conditions - Designee Review

Discussion:

This is a research project funded by the American Cancer Society. There are racial ethnic disparities in cancer mortality in patients with non-small cell lung carcinoma (NSCLC) and one of the main reasons is that patients aren't getting the guideline concordant treatment for early stage of Non-Small NSCLC. The study aims to understand what these factors are and how they influence whether patients receive or do not receive guideline concordant treatment for early-stage NSCLC.

Researchers plan to do thirty qualitative interviews with patients as well as with providers and they will send invitations to about fifty of each of those groups. They also plan to use the qualitative data to develop a quantitative survey for both patients and providers, to recruit from the Los Angeles County Cancer Surveillance Program (CSP). In the final part of the project, researchers will do some geocoding to identify hotspots where there tend to be a lot of the modifiable risk factors for receiving guidelines.
Researchers are only requesting approval for the first part of the project, which is the qualitative interviews. The response to the “Recording” section of the application should be changed from “No” to “Yes.” The number of phone calls is the same for the providers and patients.
A thank you visa gift card will be provided. There is a small fee that researchers will pay on their end and the patients can use the gift cards anywhere, but it does have an expiration within two years.

Researchers should cover not only physician surveys but also patient surveys and interview transcripts in the “Risk Description” section of the application. Also, negative emotional responses should be described for the interviews. They also clarified that the patient’s ID number is a registry ID number, and they will update the registry on the status of patients that participate so they need the registry ID number to link back to the registry information. The Social Security number is included in the registry file and is only used for the purpose of tracing patients.

Researchers need to update the list of requested variables and attach a new list of variables from the California Cancer Registry (CCR) that includes Social Security Number (SSN). Researchers explained about the reasons that physicians will receive one hundred dollars cash, but the patients receive only forty dollars in the form of a gift card for the same amount of time and effort.

Researchers said that the reason behind the cash versus the gift card is that they will interview and survey smaller number of physicians than patients, but they clarified that they could provide gift cards to the physicians as well. Researchers provide only forty dollars gift card to

the patients to prevent coercion. They said providing higher amounts to the physicians is a requirement based on their previous experiences with other studies involving physicians. Also, they included a higher amount for physicians because it is for a qualitative interview with a smaller group of physicians and the grant is able to fund a higher amount. Also, higher incentive for physicians captures their attention. Researchers clarified that the gift card is already activated when patient gets it, and the additional amount is paid by the grant with no monthly or other fees.

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

1. **Change the response in the "Recording" section of the application from "No" to "Yes."**
2. **Expand the text in the "Risk Description" section of the Protocol, to include the protection against loss of confidentiality in patient surveys and interview transcripts in addition to physician surveys.**
3. **Describe and include protection against the negative emotional response for interviews in the "Risk Description" section of the Protocol.**
4. **Attach the appropriate list of variables that includes Social Security Number (SSN).**

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

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

2. Project # 2023-076 (Palacio)
   Title: California Subminimum Wage to Competitive Integrated Employment (SWTCIE) Project (CSP) – A Program Evaluation
   PI: Meera Adya, PhD, JD, MA, BA (Hons)
   Co-PI: Chip Kenney, M.S.
   Board Decision: Approved Pending Conditions - Designee Review

Discussion:

Researchers from the San Diego State University (SDSU) Interwork Institute have planned to conduct a comprehensive evaluation of the California Department of Rehabilitation's Subminimum Wage to Competitive Integrated Employment (SWTCIE) Project which is funded by the Department of Education's Rehabilitation Services Administration (RSA). Researchers have addressed Dr. Palacio's comments regarding consent forms. Current application only covers the data that was provided in the spreadsheet about demographic information, past relevant education, and information related to employment experience, services and supports that the Department of Rehabilitation (DOR) consistently collects.

Dr. Schaeuble mentioned, "The letter of support and the data Security letter attached to the project's application were very comprehensive and informative.

In the second page of the adult consent form in the "Participant Confidentiality" section, has been mentioned, "your child's/conserved consumer's identity will be kept confidential" and on the same page in the "Questions about the Study" section, it has been mentioned, "If you have questions about your child's/conserved consumer's rights as a participant, you may contact the Committee for the Protection of Human Subjects" and Dr. Schaeuble mentioned these sections should be updated because they should be referring to adults and not parents.

Ms. Lund clarified that all translations have to be standardized and approved before they can be implemented as part of the study. Principal Investigator (PI) confirmed that they would submit the translated materials through an amendment application and the translated documents would not be employed until receiving approval for them.

Ms. Lund mentioned, "The recruitment materials are targeted at staff, and they have statements with information about recruitment into the research study but there is not any specific recruitment material that potential subjects could see to consider whether or not they want to participate" and the PI agreed to develop a document that is framed to the reader who would be providing the consent.

Dr. Bazzano mentioned, "Since many of the consumers of the Department of Rehabilitation (DOR) have disabilities, it is important to ensure all materials are meeting the standards to achieve 508 compliance. Principal Investigator (PI) confirmed that every document that the Department of Rehabilitation (DOR) provides is accessible and 508 compliant and they provide all accommodations as needed, including large prints, interpreters, sensory accommodations for deaf or blind people and interactions are meant to be in person, and they are meant to be an evolving conversation that allows for fully informed consent.

Dr. Bazzano recommended researchers to provide more context of how they could ensure that somebody with intellectual disability is understanding what they're being required to do in the

evaluation and the PI of the project confirmed that they are very sensitized to the issues related to people with intellectual disability and they plan their project accordingly.

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

1. **Update the consent form to ensure they are not mis-framed.**
2. **Develop a FAQ sheet as a reference or recruitment material for the individuals who would be consenting to the project to ensue informed consent.**
3. **Provide pictorial or graphic means into the FAQ sheet to enhance the information for the individuals.**
4. **Confirm with the department providing all recruitment materials that all materials are 508 compliant and provide a statement regarding that.**

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

Total=8 In Favor-6, Opposed-0, Abstained-2

3. Project # 2023-074 (Dickey)
   Title: Evaluation of Comprehensive Medication Management (CMM) Process Implementation and Its Impact on Patients with Poorly Controlled Diabetes and Hypertension
   PI: Roy Ahn, ScD
   Co-PI: Mithuna Srinivasan, PhD
   Board Decision: Approved Pending Conditions - Designee Review

Discussion:

This project evaluates the comprehensive medication management program that is implemented by a team at the University of Southern California (USC). Researchers at the National Opinion for Research, University of Chicago (NORC) are seeking to conduct an implementation evaluation to see how the program was implemented, what are barriers during implementation of the program, and what might be some lessons learned for other implementers. Researchers plan to do an individual level outcomes evaluation for the intervention group, and for a matched control group. Researchers will do a cost evaluation to understand the implementation cost from USC's perspective.
This project is largely a data-only project, and the interview component is only for interviewing two patients.

Researchers clarified that they are subject to a limited number of interviews to comply with the Office of Management and Budget (OMB), Paperwork Reduction Act (PRA) and since their interviews include both, discussions with program implementers and patients, they could only do two patient interviews to comply with OMB requirements.

Dr. Dickey suggested to include statements to the recruitment materials and surveys to indicate that participating is purely voluntary, and any information they provide will be confidential and will not affect their health care. Researchers have addressed Dr. Dickey’s comments.

Dr. Schaeuble mentioned, “The medical number is a unique identifier for people and should be listed in the project application as HIPAA identifiers and it is important that the list of HIPAA identifiers in the application be accurate.” Researchers agreed to replace the medical number with just a randomly generated identifier.

Researchers have requested a HIPAA waiver in the submitted application because they have requested some HIPAA identifiers including, Zip Codes and dates of service.

Dr. Schaeuble mentioned, “ The two consent forms claim there is no risk for the people involved which is true for program staff but might not be true for patients and it is necessary to inform the patients about the minimal risk. Researchers will add statements in the consent form to inform patients about the minimal risk of the loss of confidentiality and some distress and will emphasize to them that they should feel free to skip any questions that they do not feel comfortable answering, and they can conclude their interview at any time that they want.

Ms. Kurtural mentioned that researchers should change their response from “No” to “Yes” in the “Covered Entity” section of the application because the California Department of Health Care Services (DHCS) is covered as a government health plan.

Motion: It was moved by Dr. Schaeuble and seconded by Ms. Lund to grant a deferred approval, one-year, minimal risk, including a HIPAA waiver, pending the following

specified minor revisions which require expedited review and approval by a CPHS subcommittee of Dr. Dickey.

1. **Medical number should be removed from the list of variables and replaced by a random identifier.**
2. **The list of HIPAA identifiers should be checked for completeness.**
3. **The consent form discussion for patients should say "minimal risk" rather than "no risk" and give a description about possible risks.**
4. **The response in the "COVERED ENTITY" section of the application should be changed from "No" to "Yes."**

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

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

4. Project # 2023-079 (Lund)
   Title: Social Influences on Sensorimotor Integration of Speech Production and Perception During Early Vocal Learning.
   PI: Sarah Bottjer, PhD
   Co-PI:
   Board Decision: Approved Pending Conditions - Designee Review

Discussion:

This study focuses on the role of social factors in very early vocal learning. The goal of this project is to investigate how social interactions mediate the ability to produce and perceive phonological patterns heard in the language environment of infants with typical hearing versus infants with hearing loss.

Researchers plan to identify potential hearing loss infants by accessing clinic records from audiology clinics. A speech language pathologist interfaces directly with audiologists to get specific levels of hearing loss. Parents of the infants with hearing loss fill out both the informed consent form and a HIPAA form to give permission to access their audiology record but the parents of the infants with normal hearing fill out just the informed consent form.
For recruiting infants with normal hearing, researchers use social media, posting flyers at daycare centers and local schools. Researchers will obtain birth records from the California Department of Public Health (CDPH) including the child's date of birth, last name, email of parents, and mailing address to send out recruitment letters.

Major avenues for recruiting parents who have infants with hearing loss include visiting various clinics, book fares, and specific events to hand out flyer, and placing ads in Facebook.
Study would like to have a minimum of twenty participants within each study group. The recruitment started in 2020. This study was submitted to CPHS for requesting approval to access birth records to improve the recruitment of subjects.

Researchers are accessing clinic records prior to the visits in order to identify infants with hearing loss to invite them to participate. The speech language pathologist has access to clinic records and will send the recruitment letter to the parents who have infants with hearing loss. Researchers have received a partial HIPAA waiver from the University of Southern California (USC) that covers the specific use of identifying the individuals from the clinic records and researchers will attach a copy of the HIPAA waiver to the application.

Ms. Lund mentioned, “The screening form to determine eligibility takes place before informed consent and researchers need to clarify on the screening form that they collect this information for the purposes of establishing eligibility, the information is confidential, and once the eligibility established they would not retain the information that they captured. Also, the same information should be included in the interviewer form and should be read to the subjects.”

Researchers will modify the study application to reflect the actual sample sizes that they expect. The consent Form should be modified to include the information that researchers will access the medical record information for the infants with hearing loss.

Researchers plan to only access the exact level of hearing loss from the audiograms and then they will merge that data with the data from their visits with those infants.
Researchers do not require additional visits for participants and additional visits are optional.

Parents who have come in for the initial visit are enthusiastic about coming back. Participants may get a t-shirt for participating in the study, but monetary compensation is strongly discouraged by study's IRB.

The subjects of the study can opt to not share their data, they can decide not to continue in the study, and they can request that their data be destroyed. Researchers will double check to ensure that the consent form has a specific statement to inform the subjects that they do not have to share their data.

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

1. **Clarify in the consent form regarding the data sharing language that the subjects don't have to share their data and it is optional.**

2. **Contain a language in the consent form regarding accessing the medical record information for infants with hearing loss.**

3. **Include a description of accessing the medical record information in the "Procedures" section of the application for specific hearing loss levels and clarify that you plan to access the medical record information from the hearing lost infants and attach it to their data.**

4. **Contain in the consent form the language for participating parents who have infants with hearing loss regarding accessing the hearing loss information from clinic records.**

5. **Include the documentation of the HIPAA waiver from another IRB in the protocol.**

6. **Include the second screening form modality.**

7. **Include the changes to sample size and clarify in the protocol that it has changed to twenty per group for a total of forty participants.**

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

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

H. Amendments – Full Committee Review Required

1. Project # 2023-023 (Dickey)
   Title: Dental Anesthesia and Sedation Research Project
   PI: Nadereh Pourat, PhD
   Co-PI:
   Board Decision: Approved Pending Conditions - Designee Review

Discussion:

Researchers submitted an amendment in order to survey thirty thousand members of the California Dental Association across the State of California to see their common practices related to dental anesthesia and sedation and their perception on barriers to providing and accessing services. The data produced by this survey will be used to better describe the use and barriers to dental general anesthesia and sedation procedures in California.
The survey will be sent out to members of the California Dental Association by emailing them and providing a link to a web-based survey. They include that the survey is voluntary, and that no individual level data will be shared back with the States.

Dr. Dickey mentioned, “The survey seemed very straightforward, asking professional questions about the professional practices. He also suggested to add the phrase "answering these questions is voluntary and your personal identity and answers will not be shared with the State." to both the recruitment e-mail and the survey. Researchers have addressed Dr. Dickey’s comments.

Dr. John Schaeuble recommended researchers to check the particular software that is being used for the online survey since they might capture some identifying information and attach it to the survey information and that is an option when researchers are setting up the survey.

Researchers clarified that there is no intention of capturing any individual level identification. Researchers will ensure that the survey has a statement indicating no confidential information provided in the survey will be shared with the State or anyone else and also the survey software does not capture any identifying information.

Motion: It was moved by Ms. Kurtural and seconded by Dr. Hess to grant a deferred approval, minimal risk, pending the following specified minor revision(s) which require(s) expedited review and approval by a CPHS subcommittee of Dr. Dickey.

1. **Include a statement in the survey that no confidential information provided in the survey will be shared with the State or anyone else.**
2. **Confirm in the application that the survey software does not capture any identifying information.**

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

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

I. Second Review Calendar

Some projects listed may have been approved by expedited review prior to this meeting and were not reviewed by the full committee.
Total Project Count (1)

1. Project # 2022-058 (Schaeuble)
   Title: Family Responses to College Financial Aid Incentives
   PI: Jesse Rothstein, PhD
   Co-PI: Ryan Fuller, EdD MA
   Board Decision: Not Approved

Discussion:

Committee members reviewed a memorandum provided by the researchers which was summarizing various legalities related to the amendment and revised protocol. The project is an effort to study family responses to the financial aid system to understand whether it is allocated efficiently. The notable difference is a change in the number of student aid Commission data that would be linked to the credit data. Researchers made an abstraction of the Free Application for Federal Student Aid (FAFSA) data to a much smaller set of variables that will then be moved over to a separate virtual machine that is isolated, where it'll be link to the credit panel data to reduce the risk of a breach.

Dr. Schaeuble shared some information provided to people and families who request their credit reports from the bureaus and explained about a document as “A Summary of Your Rights Under the Fair Credit Reporting Act. The document generally suggests to people that their information is only going to be used for credit granting purposes rather than for any other purpose and there's no opportunity to opt out.

Dr. Evan White clarified that most people never see that document because it is not provided at the beginning of any credit application.

Dr. Dickey mentioned that the document uses the word “usually” and not “only” to say the information “usually” is to be used for credit granting purposes and people can reasonably assume that there may be other uses for it that are not only for credit granting purposes.

Dr. Schaeuble explained the FAFSA application and mentioned when people fill out their application form, they would not be informed properly of the possibility that their data might be used for research purposes. There is only a link in the FAFSA form that opens another document to explain about routine uses of FAFSA data which has pointed, “The Department may disclose records to a researcher if the Department determines that the individual or organization to which the disclosure would be made is qualified to carry out specific research related to functions or purposes of this system of records. The Department may disclose records from this system of records to that researcher solely for the purpose of carrying out that research related to the functions or purposes of this system of records. The researcher shall be required to agree to establish and maintain safeguards to protect the security and confidentiality of the disclosed records.”

Dr. White mentioned, “ The California Student Aid Commission (CSAC) has authority over the Free Application for Federal Student Aid (FAFSA) records that are filled out in California, and

CSAC is the agency to whom we need to go to receive approval for a project like this and the people who have authority to oversee the related laws have routinely allowed data linkages between financial aid data and other data."

Dr. Schaeuble mentioned, "It is not fair to the families that their data is being used, not only without consent, without an ability to opt out, without a meaningful disclosure that their data might be used in this way, but even the only document that they are likely to see has a language that suggests to the contrary that their data is being protected against other uses that they might not anticipate and this is contrary to the first principle in the Belmont report, "Respect for Persons."

Dr. Schaeuble mentioned, "There were suggestions to limit the review to a restricted approach based on the Information Practices Act (IPA)."

Dr. Schaeuble shared a document as "Congressional summary of information related to the Higher Education Act (HEA).The document specifies that forthcoming changes would reduce the amount of information collected on the FAFSA form, to reduce the burden on families for what information they need to provide. It means the federal changes will support simplifications and a lesser complexity in the nature of the calculation for eligibility while the researchers are requesting to probe more deeply into families' finances by adding credit variables to an ongoing project. He also mentioned, "There is certainly enough individual information that would be unique for one family compared to another within the data and such identification is a potential possibility."

Ms. Jennifer Schwartz mentioned, "This project is involving existing state data and not involving human subjects and the authority of the Committee is around protecting that data and is limited to the criteria in the Information Practices Act (IPA). If the California Student Aid Commission (CSAC) that's providing data for this research, felt this data was adequately de-identified, they could actually just provide this data under the Public Records Act (PRA). If projects are only reviewed based on the criteria in the IPA, the board is not acting as an IRB for these projects, the Federalwide Assurance (FWA) does not apply and the authority of the Board is limited to evaluating the criteria in the IPA to decide if researchers have provided enough assurances that the criteria are met, and if the criteria are met in the IPA, then my recommendation would be to approve the project."

Dr. Dickey mentioned, " The researchers have authority to have access to the data and that's been determined by other authorities and other laws and the main focus should be if the researchers have provided a plan sufficient to protect personal information from improper use and disclosures, including sufficient administrative physical, technical safeguards to protect personal information from reasonably acceptable threats." Dr. Dickey asked if any committee members have concerns that the researchers have not provided a sufficient plan. No committee members expressed a concern. Dr. Dickey asked Dr. White to explain what a "virtual machine" is.

Dr. White explained, "A virtual machine is like a standalone computer. There are large servers, and they create separate virtual machines that are walled off from each other where there's no way to get information in or out and there is no ability to transfer data out of our system. The virtual machines cannot communicate with each other and with the outside and they do not have any access to the Internet. After connecting to them, you can work on the data there, but you can't get any of the data off. We have the full FAFSA data already on a virtual machine and this amendment is requesting approval to link a portion of the FAFSA data with a portion of the

credit data and that would then be moved by our IT manager to an entirely separate computing environment and in order to do analysis on the linked data they would have to use it only on that virtual machine. A team in the California Policy Lab (CPL) takes encrypted versions of the identifiers which are provided by CSAC and the Credit Bureau and do the linkage by using a technique called hash linkage, or a privacy protected record linkage. CSAC and the Credit Bureau do the encryption and the encryption is a one-way type of encryption and doesn't allow for decryption. If you wanted to replicate the encryption, you would have to have a special password as “SALT”, but even if you had that, you would still have to reproduce it and you could never decrypt all of the data and only CSAC and the Credit Bureau have the “SALT” and only people mentioned in the protocol in IRBManager will have access to the linked data.”

Ms. Carrie Kurtural mentioned that there was plenty of characteristic data in the project application and there would be a possibility that the data being linked together would be identified and recommended to limit the information regarding the exact dates of some events to only “year” and Dr. Rothstein agreed.

Dr. Dinis mentioned, “The people whose data is being used for the purpose of this amendment don't have a chance to consent which is unfair. This project goes to the edge of being unethical because some of these populations are vulnerable populations applying for aid and they don’t have protections and it is not acceptable that we can in one hand operate as an IRB with the Federalwide Assurance (FWA) for some projects but on this occasion we're supposed to step back and be a second committee for the state of California.”

Dr. Schaeuble said, he would make a motion to approve and vote against the motion because he found it very troubling to be asked to set aside any concern about fairness to the people whose information would be used, and to follow a checklist of requirements under the IPA, which does not reflect the moral compass that he tried to abide by. Dr. Schaeuble moved that the committee approve the amendment with a condition that specific dates be removed from the requested variables, and only years be substituted instead.

Dr. Dickey clarified, “If researchers make changes to the amendment, they can reapply”, and Dr. Ruiz agreed.
Dr. Bazzano said, “I was not convinced that there was enough data protection and researchers can make a number of changes and resubmit the amendment application, and the Committee would have to look at the project again.”

Motion: It was moved by Dr. Schaeuble and seconded by Ms. Kurtural to grant the amendment a deferred approval under the Information Practices Act (IPA) pending the following specified revision(s), which require(s) expedited review and approval by a CPHS subcommittee of Dr. John Schaeuble.

—All specific dates should be removed from the requested variables, and only years be substituted instead.

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

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

J. 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 (13)

K. Projects Requiring Periodic Review Only (Including Greater than Minimal Risk)

Some projects listed may have been approved by expedited review prior to this meeting and were not reviewed by the full committee.
Total Project Count (29)

K1. Projects Requiring Periodic Review Only (Including Greater than Minimal Risk) – Administrative Action Taken

Some projects listed may have been approved by expedited review prior to this meeting and were not reviewed by the full committee.
Total Project Count (139)

L. Projects with Major Revisions Requiring Periodic Review

Some projects listed may have been approved by expedited review prior to this meeting and were not reviewed by the full committee.
Total Project Count (25)

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

N. Exemption/Determination Requests

Total Project Count (18)

O. Final Reports

Total Project Count (15)

P. Public Comments

None.

Q. Next Meeting

The next meeting will take place on Friday, August 4, 2023.

R. Adjournment

This meeting was adjourned at 2:00 PM.