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)

Friday, December 5, 2025
8:30 a.m.

Zoom:
CPHS December 5, 2025, Full Committee Meeting

Meeting ID: 160 967 0422
Passcode: 869388

Location:
Office of Technology and solutions integration (OTSI)
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Meeting ID: 160 967 0422

MINUTES

Members
Larry Dickey, MD, MPH, Vice Chair
Catherine Hess, PhD
Juan Ruiz, MD, DrPH, MPH
Maria Dinis, PhD, MSW
Laura Lund, MA
Philip Palacio, EdD, MS
John Schaeuble, PhD, MS
Allen Azizian, PhD
Maria Ventura, PhD
Jonni Johnson, PhD
David Lang, PhD
Lemeneh Tefera, MD, MSc

Remote Attendees
Allen Azizian, PhD
Maria Dinis, PhD, MSW
David Lang, PhD

Alternate Member
Millard Murphy, JD

CDII
Agnieszka Rykaczewska, Deputy Director

CPHS Administrator
Agnieszka Rykaczewska, PhD

Committee Members Present in Person:
Larry Dickey, MD, MPH
Maria Ventura, PhD
Catherine Hess, PhD
Philip Palacio, EdD, MS
John Schaeuble, PhD, MS
Lemeneh Tefera, MD, MSc
Laura Lund, MA

Committee Members Present Remotely:
Allen Azizian, PhD
Maria Dinis, PhD, MSW
David Lang, PhD

CPHS Staff Present in Person:
Agnieszka Rykaczewska, PhD
Sussan Atifeh
Nicholas Zadrozna
Karima Muhammad

Also, Present Principal Investigators and Associate Investigators Remotely:
Joshua Fenton (UC Davis Health)
Marykate Miller (UC Davis Health)
Kerry Padgett (California Department of Public Health)
Jessica Khouri (California Department of Public Health)
Bridgette Lery (Urban Institute)
Jaclyn Chambers (Urban Institute)
Michael Hoyt (University of California, Irvine)
Shannon Whaley (Public Health Foundation Enterprises)
Meg Demment (Public Health Foundation Enterprises)
Danny Azucar (Rescue Agency)
Sami Kitmitto (American Institutes for Research)
Colleen Boggs (American Institutes for Research)
Leanne Elliott (American Institutes for Research)
Shannon Keuter (American Institutes for Research)
Lisa White (American Institutes for Research)
Anlan Zhang (American Institutes for Research)

Others Present Remotely:
Cheryl Byers (Advarra)

A. Welcome

a) Announcing CPHS Transitions

Dr. Larry Dickey, CPHS Vice Chair, called the meeting to order. Sussan Atifeh took roll and confirmed that a quorum was established. Dr. Dickey then acknowledged CPHS's recent move to OTSI and shared that he attended Dr. Lowe's funeral at the National Cemetery in Dixon.

Dr. Dickey informed the committee that he is serving as Acting Chair, as Dr. Hess has accepted a new position outside of CalHHS. Because this new role is outside of CalHHS, Dr. Hess is no longer eligible to serve as Chair. A resolution regarding the appointment of a new CPHS Chair is expected by the next committee meeting.

B. Administrative Update

a) Share CDII update and introduction to new CPHS consultants

Dr. Agnieszka Rykaczewska informed the committee that the Data De-Identification Guidelines (DDG) were recently updated to version 2.0 and that the updated guidelines and template have been uploaded to the CPHS website.

She explained that the DDG outlines the method and process by which California Health and Human Services (CalHHS) departments de-identify confidential or sensitive data prior to release. This approach is essential for balancing privacy protections with transparency.

The CalHHS DDG peer review team released the first version of the guidelines in 2016. Since then, the team has conducted research, reviewed best practices, and engaged with stakeholders to develop the new version 2.0.

Key updates include a consistent risk-scoring methodology based on population sizes and updated population tables reflecting 2020 census data. The new version also introduces risk-scoring procedures for additional demographic variables, including sexual orientation, gender identity, immigration status, insurance coverage, expected payer, and public assistance, among others.

Version 2.0 adds a walkthrough table to guide users through the system and clarify how to apply the scoring tables. It also includes guidance for special scenarios such as data with increased specificity, high-risk populations, and considerations related to artificial intelligence (AI).

Additionally, version 2.0 addresses gaps in the original guidelines. For example, version 1.0 did not provide guidance for survey data, whereas the new version now includes this information.

CalHHS departments have until December 2026 to adopt departmental DDGs consistent with the version 2.0 template.

Dr. Rykaczewska asked the committee for questions or comments. Dr. Schaeuble recommended extracting the table on page 9 of the DDG and providing a link to it in the CPHS application, noting that researchers often misunderstand what constitutes personal information. Dr. Rykaczewska agreed that this change should be made.

Dr. Dickey asked how researchers should be advised regarding the DDG if departments have until 2026 to adopt version 2.0. Dr. Rykaczewska recommended providing the version 2.0 guidance, as the risk scores remain the same, but the new version offers more detailed information.

Ms. Lund asked about the status of the Research Request Form. Dr. Rykaczewska explained that the project is still underway but progressing more slowly due to limited CPHS resources. Nicholas Zadrozna is leading the effort. In recent months, meetings have been held with the CalHHS Information Security Officer to review and update the security-related questions. Part of the update will include adding an attestation section for researchers' Chief Information Officers, who have the appropriate expertise in data security. Ms. Lund asked whether the consultants were involved in this effort. Dr. Rykaczewska stated that they have not yet been involved but will receive a copy in the future.

Dr. Schaeuble noted that a few years ago, a researcher submitted a checklist summary with the Data Security Letter outlining how each component was met and identifying any exceptions. He mentioned that a recent researcher did the same. Dr. Rykaczewska shared that Sussan Atifeh had recently forwarded that document to her and that it was a helpful resource.

Dr. Rykaczewska then informed the committee that the Department of Health Care Services (DHCS) recently contacted the CPHS Administrative Team and Chairs seeking clarification on HIPAA waiver requirements. DHCS stated that they will only accept HIPAA waivers issued by CPHS and will no longer accept waivers

granted by other institutions or IRBs. DHCS made this change because they know the CPHS HIPAA waiver meets specific requirements, and they do not have the capacity to review waivers issued by other IRBs.

However, current CPHS Policies and Procedures state that CPHS will not consider issuing a HIPAA waiver if one has already been granted by another IRB. CPHS legal counsel reviewed the relevant laws and confirmed that there is no legal restriction preventing CPHS from issuing a HIPAA waiver even if another IRB has already granted one.

Dr. Rykaczewska proposed updating the Policies and Procedures to allow CPHS to consider issuing a HIPAA waiver when requested by researchers, even if another IRB has already granted one.

Ms. Lund noted that CPHS has several other needed updates to the Policies and Procedures, and over a year ago the committee agreed to maintain the existing policies until all changes could be incorporated together. She asked whether this change would need to take effect immediately, given that DHCS will not accept HIPAA waivers unless they come from CPHS, which could place researchers in a difficult position. She also questioned why this change should be prioritized over other important updates. Dr. Rykaczewska explained that DHCS has repeatedly expressed concerns about releasing data when researchers do not have a CPHS-issued HIPAA waiver. She opened the discussion to the committee.

Dr. Tefera expressed confusion about why DHCS is concerned about HIPAA waivers from other IRBs. Dr. Dickey suggested that DHCS receives requests from many different IRBs and that reviewing each waiver would require significant resources. Dr. Tefera noted that many university-based IRBs would be affected by this change.

Dr. Dickey added that IRBManager already allows researchers to request a HIPAA waiver regardless of the department from which they are requesting data.

Ms. Lund stated that she supports the change in principle but does not support updating the Policies and Procedures to reflect it unless other important changes are implemented at the same time.

Dr. Dickey noted that the Agency could implement these changes without committee approval if necessary, and DHCS could request that CalHHS move forward even if the committee objects.

Dr. Ventura asked about the expected timeline for the draft of the new Policies and Procedures. Dr. Rykaczewska stated that the Advarra consultants are currently reviewing the document and have begun interviewing committee members.

Advarra consultant Cheryl Byers informed the committee that the draft is expected to be completed around February 2026 for review by the Chairs and the CPHS Administrative Team. Dr. Rykaczewska stated that the draft will be shared with the full board before any changes are recommended to the CalHHS Secretary. Dr. Schaeuble asked about the committee's role in providing input. Dr. Rykaczewska assured him that committee members will have adequate time to review and provide recommendations. Ms. Byers added that this topic should appear on the agenda for a future board meeting in February or March 2026.

Dr. Rykaczewska asked whether the committee agreed that all changes to the Policies and Procedures should be made at once rather than implemented piecemeal. She will inform DHCS of the board's decision.

There were no questions from the public.

C. Nomination of New CPHS Chair

Dr. Rykaczewska informed the committee that, with the recent news of Dr. Hess stepping down from the Chair position, CPHS is not yet prepared to make a decision on a replacement. The decision will be deferred to the February agenda to allow additional time for consideration.

She also clarified that Adam Dondra was listed on the agenda for this item because the CDII Director position is currently vacant, and he is fulfilling those responsibilities in the interim.

There were no questions from the public.

D. Review and Approve of Meeting Minutes

Dr. Dickey asked whether there were any comments or public comments on the meeting minutes from the October 3, 2025, Full Board Meeting. There were no questions or comments from the committee or the public.

Motion: It was moved by Dr. Hess and seconded by Dr. Ventura to approve the October 3, 2025, Full Board Committee Meeting Minutes.

Approve: Dr, Hess, Dr, Hess, Azizian, Dr. Dinis, Ms. Lund, Dr. Palacio, Dr, Schaeuble, Dr. Tefera, Dr. Lang
Oppose: None
Abstain: None
Absent: Dr. Ruiz, Dr. Johnson
Total=9 In Favor-9, Opposed-0, Abstained-0

E. Projects with Reported Adverse Events and/or Deviations

1) Project #:	**2025-038 (Dickey)**
Title:	Rigorous Evaluation of California Policies to Disseminate Emergency Department-based Services for Opioid Use Disorder
PI:	Dr. Fenton
Board Decision:	Approved Pending Conditions- Submitting an Amendment

Discussion:

The Principal Investigator (PI) from the University of California, Davis (UCD), presented the study along with the project coordinator. The study is a large program evaluation that uses Medi-Cal claims data to assess the impact of CA Bridge, a program designed to support substance use services in California emergency rooms. The research team is analyzing how exposure to these services affects patients' use of medications for opioid use disorder, their use of outpatient substance uses services, and the outcome of fatal overdoses.

To study fatal overdoses, the team obtained approval from the Committee for the Protection of Human Subjects (CPHS) to access California death records. These records included partial SSNs (Social Security Numbers) and other patient identifiers, which were necessary to link overdose deaths to Medi-Cal claims. The team followed the approved procedures through the CCW (Chronic Conditions Data Warehouse) and its VRDC (Virtual Research Data Center), using a Finder File to match death records with claims.

The data were encrypted and sent to the CCW vendor on a thumb drive, following the vendor's instructions. However, when the package arrived, the envelope was torn open, and the thumb drive was missing. This created a data loss incident involving patient information. The team reported the incident to CPHS, the California Department of Public Health (CDPH), and the University of California, Davis (UCD) IRB.

Researchers noted that the thumb drive containing patient information had been password protected, and the password was never sent with the device. The procedure requires sending the password separately to the data processor, which provided an additional layer of protection. They clarified that the encrypted password for the data was never sent, because the procedure requires waiting until the vendor confirms receipt of the package before the password is shared via encrypted email.

The PI further explained that the research team has been in contact with CCW, and they learned that, because they are working within the CCW's Virtual Research Data Center (VRDC), future data transfers can be uploaded directly into the secure system rather than being sent by courier mail. This method was not included in the printed instructions they initially received, but it is now understood to be a more secure approach. The PI

stated that the University of California, Davis Institutional Review Board (IRB), the Information Technology department, and the Compliance office were all informed of the incident. The Compliance office investigated and issued a report, closing the matter. The UC Davis IRB is awaiting the compliance report before issuing its final determination.
The PI explained that the data vendor requires Advanced Encryption Standard (AES) with a 256-bit key, implemented through 7-zip software. This is considered a federal standard for privacy protections. The California Department of Public Health (CDPH) privacy officers reviewed the incident and determined that it did not trigger notification requirements under applicable laws, and the matter was closed.

Committee members discussed the proposed change in data transmission methods. They agreed that uploading data directly to the VRDC is a secure improvement but noted that a formal amendment to the project will be required. The committee recommended that the researchers submit such an amendment.

Motion: Ms. Lund moved, and Dr. Palacio seconded, that the Committee accept the adverse event report and the mitigation measures taken to date. The Committee further required that the data transmission method be changed to a more secure process and that an amendment be submitted to reflect this change.

Approve: Ms. Lund, Dr. Palacio, Dr. Azizian, Dr. Dinis, Dr. Hess, Dr. Lang, Dr. Schaeuble, Dr. Tefera, Dr. Ventura.
Oppose: None.
Abstain: None.
Absent: Dr. Ruiz, Dr. Johnson.
Total=9 In Favor-9, Opposed-0, Abstained-0

2) Project #:	**12-10-0804 (Dickey)**
Title:	Using Infant Feces and Serum for Polymerase Chain Reaction (PCR) and Assay with Large Immunosorbent Surface Area (ALISSA) Assay Development and Validations and for Intestinal Microbiome and Clostridium Botulinum Genomic Characterizations
PI:	Dr. Padgett
Board Decision:	Approved Pending Conditions – Designee Review

Discussion
Dr. Carrie Padgett, Principal Investigator (PI) and Chief of the High-Risk Pathogens Center at the California Department of Public Health (CDPH), attended the meeting with staff from the Infant Botulism Treatment and Prevention Program (IBTPP). The team described their project, which uses leftover serum and feces from infants suspected of having infant botulism to develop improved diagnostic tests.

An adverse event was reported on September 28, 2025, when hospital staff mistakenly drew a new blood sample for research instead of providing leftover serum from a prior clinical draw. The infant had already been discharged when the sample reached the CDPH laboratory. The error was attributed to human misunderstanding of the request. While rare, the researchers acknowledged that similar incidents had occurred before.

As corrective action, the team created a script for IBTPP staff to use when requesting samples and revised fax cover letters to emphasize that no additional blood draws should be performed. They asked the Committee for the Protection of Human Subjects (CPHS) for guidance on whether the sample obtained in error could be used.

The committee discussed whether the corrective actions were sufficient and how to handle the improperly collected sample. Members raised concerns about communication gaps between hospital laboratories and clinical staff. The researchers explained their usual process, which includes parental consent and faxed instructions, but acknowledged that requests are often directed to laboratory staff rather than managers, which

may cause confusion. They proposed clearer wording in fax subject lines and considered placing instructions in the electronic medical record (EMR).

Committee members emphasized that parental consent is given with the understanding that no new blood draws will occur. They agreed that parents must be informed of the adverse event, regardless of whether re-consent is sought for use of the sample. The researchers explained they had delayed notification to avoid burdening families during a record-breaking year of infant botulism cases linked to a formula-related outbreak.

The committee reviewed the frequency of such events, noting that since 2021 the program had received about 100 serum samples, with two adverse events in that period. Over the project's 12-year history, 148 samples were collected prior to 2021. Members agreed that incidents are rare but stressed the importance of preventing future errors.

The committee determined that adverse events must always be reported to CPHS chairs, who will decide whether immediate parental notification is required. In this case, they agreed that waiting for committee review before notifying parents was appropriate. They concluded that the corrective actions taken were sufficient and that broader protocol changes were not needed.

No public comments were provided.

Two motions were approved:

Motion 1: Ms. Lund moved, and Dr. Hess seconded, to accept the adverse event report and the mitigation measures taken to date. The Committee further recommended that the researchers submit an amendment with revised wording for communications with hospitals and collaborate with hospital staff to ensure the information is entered into the electronic medical record (EMR) so that the clinical team is informed.

Approve: Ms. Lund, Dr. Hess, Dr. Azizian, Dr. Dinis, Dr. Palacio, Dr. Lang, Dr. Schaeuble, Dr. Tefera, Dr. Ventura.
Oppose: None.
Abstain: None.
Absent: Dr. Ruiz, Dr. Johnson.
Total=9 In Favor-9, Opposed-0, Abstained-0

Motion 2: Ms. Lund moved, and Dr. Ventura seconded, that the Committee ask the researchers to notify the parents of the adverse event and permit the use of the blood drawn from the infant if the parents provide verbal consent for its use in the study. The verbal consent language will be submitted as part of the amendment pursuant to this adverse event.

Approve: Ms. Lund, Dr. Ventura, Dr. Azizian, Dr. Dinis, Dr. Hess, Dr. Palacio, Dr. Lang, Dr. Schaeuble, Dr. Tefera
Oppose: None
Abstain: None
Absent: Dr. Ruiz, Dr. Johnson
Total=9 In Favor-9, Opposed-0, Abstained-0

3) Project #:	**2023-057 (Palacio)**
Title:	Evaluating California's Guaranteed Income Pilot Program
PI:	Dr. Lery
Board Decision:	Approved

Discussion:
This project is being conducted by the Urban Institute in partnership with the California Department of Social Services (CDSS). The evaluation involves providing monthly guaranteed income payments for 18 months to

specified groups, including former foster youth in California, and assessing program outcomes. Under the project's data security plan, CDSS is permitted to access and manage personally identifiable information (PII), while the Urban Institute is not allowed to receive PII and typically receives only de-identified data or first names.

The Principal Investigator (PI) explained that an adverse event occurred on October 17, when a CDSS staff member inadvertently emailed payment information about youth in the study to three Urban evaluation team members, including the PI. Although the email was not intended to transmit PII, the attached spreadsheet contained both first and last names for approximately 700 youth. Upon opening the email and noticing the presence of PII, the PI immediately deleted it and reported the incident to Urban's Institutional Review Board (IRB) and information technology staff, who provided guidance on secure deletion. The other two team members deleted the email without opening it. Urban's IRB and technical staff were satisfied with these actions, and the project team subsequently reported the event to CPHS.

In response to the incident, the research team permanently deleted and purged the email, confirmed with Urban's technical team that no further system-level action was needed, and alerted CDSS to reinforce the policy that PII should not be sent to the research team via email.

The PI noted that all state and evaluation staff had previously received training not to send PII by email, and that CDSS and Urban typically use a secure file transfer protocol (SFTP) for data sharing. The CDSS staff member who sent the email had been aware of these procedures but forgot them in this instance. The Committee emphasized the importance of preventing such lapses and discussed plans to send periodic reminder emails on a quarterly basis, and to strengthen onboarding and refresher training for both new and existing staff. Additional suggestions included incorporating routine reminders into project meetings and encouraging staff to verify that attachments do not contain PII before sending or opening them.

The PI also clarified that youth who enroll in the guaranteed income program agree that their data may be used by the state for evaluation purposes. However, Urban continues to minimize its direct access to PII. The Committee further clarified that while participants may have given general permission for their data to be used, the researchers do not have authorization under the current research protocol to receive or share PII.

To conclude, the Committee recommended that the project team maintain its prohibition on emailing PII, continue sending quarterly reminder emails to relevant staff, and enhance training efforts for both state and evaluation personnel to reinforce best practices in data security and PII handling.

Motion: Dr. Palacio moved and Dr. Schaeuble seconded to accept the adverse event report and mitigation efforts currently made. The Committee recommends that quarterly reminder emails be sent to staff and strengthened training measures to prevent the reoccurrence of this event.

Approve: Ms. Palacio, Dr. Schaeuble, Dr. Azizian, Dr. Dinis, Dr. Hess, Lang, Dr. Ms. Lund, Dr. Tefera, Dr. Ventura.
Oppose: None.
Abstain: None.
Absent: Dr. Ruiz, Dr. Johnson.
Total=9 In Favor-9, Opposed-0, Abstained-0

F. New Projects – Full Committee Review Required

1) Project #:	**2025-172**
Title:	Understanding Adverse Biopsychosocial Outcomes and Unmet Needs Among Long-Term Young Adult Survivors of Testicular Cancer
PI:	Dr. Hoyt
Board Decision:	Deferred Approved Pending Conditions – Designee Review

Discussion:

The Principal Investigator (PI) from the University of California, Irvine (UCI) presented the project and mentioned that it is focused on longer-term survivors of testicular cancer who are still young adults. The study is a supplement to a parent grant funded by the National Cancer Institute. The plan is to recruit participants and conduct a one-time data collection using self-report questionnaires. The focus is on symptoms, quality of life, and relationships as they relate to survivorship, with the idea of assessing the appropriateness of intervention approaches for future studies.

The primary reviewer of this project, Dr. Schaeuble, noted that the survey was lengthy and included many personal questions. He raised concerns about the plan to maintain a separate file linking names of respondents with survey ID numbers. He suggested reconsidering this approach and instead providing each participant with a unique access code without retaining a list that connected names to survey IDs. Dr. Schaeuble emphasized that unlinking names from survey data would better protect confidentiality and likely improve the quality of responses.

The PI and research staff explained that recruitment would be through the California Cancer Registry. Each individual would be sent a unique code with their recruitment materials, which they would enter at the start of the REDCap survey. Names and codes would be kept completely separate, accessible only to the study coordinator, and destroyed after data collection. The PI acknowledged that until the list was deleted, there would be a link between names and codes. Dr. Schaeuble reiterated that retaining such a list created potential identifiability and questioned its necessity. The PI agreed to clarify whether the Cancer Registry required reporting of ineligible participants and stated that if not required, the linkage could be removed.

Dr. Schaeuble also asked about references to medical record numbers in the protocol. The PI explained that through an “Honest Broker” process at the university, eligibility criteria would be submitted to the medical records system, which would return a list of medical record numbers. The study team would then use those numbers to obtain contact information. Once contact information was obtained, medical record numbers would be destroyed. The Committee requested clarifications in the protocol to reflect this process.

Dr. Schaeuble further commented on the resource sheet provided to participants. It was noted that while the sheet contained extensive cancer information, it lacked resources for emotional or mental health support. The PI agreed to enhance the resource sheet to include more supportive materials.

The Committee raised additional points and noted that a HIPAA waiver was not necessary for self-report data or Cancer Registry data, though the University of California IRB had provided a limited waiver for medical record screening. They also questioned the request for an informed consent waiver. The research team explained that the University of California, Irvine IRB required only a study information sheet for online surveys rather than signed consent forms. The Committee emphasized the distinction between waiving informed consent and waiving documentation of consent and requested that an informed consent process be maintained. It was clarified that the information sheet had been updated to include an explicit choice for participation.

The Committee also noted that the California Cancer Registry brochure was required to be provided to participants. The PI asked whether a link to the electronic brochure would suffice, and the Committee agreed that this would be acceptable if consistent with registry requirements. The Committee recommended that the brochure be included in the initial mailing to potential participants.

Motion: Dr. Schaeuble moved, and Dr. Ventura seconded to grant a deferred approval, for a period of one year, classified as minimal risk, pending the following specified revisions which require expedited review and approval by a CPHS subcommittee of Dr. Schaeuble:

The survey will be made anonymous by not retaining a linkage between names and ID numbers for the survey and having a separate survey for contact information for the gift card. If there is a requirement to report to CCR individuals who did not pass the screening question, the protocol would come back to the reviewer for consideration.

Protocol will explain that medical record numbers will not be retained once contact information has been extracted for potential participants not coming from CCR.
The resource sheet will be revised to provide some emotional support resources.
The CCR brochure will be included in the initial mailing to potential participants from that source.

Approve: Dr. Schaeuble, Dr. Ventura, Dr. Hess, Dr. Azizian, Ms. Lund, Dr. Lang, Dr. Palacio, Dr. Tefera.
Oppose: None.
Abstain: None.
Absent: Dr. Ruiz, Dr. Johnson, Dr. Dinis.
Total=9 In Favor-9, Opposed-0, Abstained-0

2) Project #:	**2025-177 (Ventura)**
Title:	Evaluation of the 2026 WIC Food Package Changes
PI:	Dr. Whaley
Board Decision:	Deferred Approved Pending Conditions – Designee Review

Discussion:
The Principal Investigator (PI) provided a summary of the project, which is related to upcoming changes to the Women, Infants, and Children (WIC) food packages scheduled for 2026.

The study will include two waves of data collection, one before the food package change in April 2026 and one approximately a year later. The goals are to assess the impact of the changes on redemption of WIC foods, participation in the program, and outcomes such as diet quality, food security, food purchasing, and perceptions of the food package. Administrative WIC data will be used to reduce participant burden, and a survey will be conducted with a random sample of approximately 20,000 individuals, aiming for 4,000 participants in the first wave.

The primary reviewer, Dr. Ventura noted that additional research team members will be added in a future amendment. She highlighted the need to clarify informed consent procedures, emphasizing that the request is for a waiver of documented written consent rather than a waiver of informed consent. She confirmed that the consent script adequately informs participants of risks, data use, and contact information.

The Committee raised concerns about recruitment materials, noting that they must clearly state that participants are being invited to take part in “Research.” The members also emphasized the need to inform participants that their survey responses will be linked to sensitive program data, that follow-up will occur a year later, and that loss of confidentiality should be listed as a risk. Clarification was requested on whether California Department of Public Health (CDPH) staff would have access to study data, which would require a data security letter. The Principal Investigator (PI) explained that survey data would be anonymized before being shared with CDPH, and identifiers would be removed prior to merging datasets.

There were no public comments.

Motion: Dr. Ventura moved, and Dr. Schaeuble Seconded to grant a deferred approval, for a period of one year, classified as minimal risk, pending the following specified revisions which require expedited review and approval by a CPHS subcommittee of Dr. Ventura:

> **1. In a future amendment, all California Department of Public Health (CDPH) research staff will be added. Until then, only those listed in the current submission will have access to the data.**
>
> **2. Clarify in the recruitment materials that this is Research: “Share your thoughts about WIC foods and shopping in a 30-minute Research survey. Receive a $10 gift card. Participation is voluntary and will not affect your WIC benefits. You can skip any questions. Take the survey [LINK HERE].”**

3. Add the risk of loss of confidentiality to the consent script. This can be word-smithed.

Approve: Dr. Ventura, Dr. Schaeuble, Dr. Hess, Dr. Azizian, Ms. Lund, Dr. Lang, Dr. Palacio, Dr. Tefera.
Oppose: None.
Abstain: None.
Absent: Dr. Ruiz, Dr. Johnson, Dr. Dinis.
Total=9 In Favor-9, Opposed-0, Abstained-0

3) Project #:	**2025-178 (Lund)**
Title:	Understanding Attitudes, Perceptions, and Behaviors toward Youth Cannabis Use in California
PI:	Dr. Azucar
Board Decision:	Deferred Approved Pending Conditions – Designee Review

Discussion:
The Principal Investigator (PI) of the project provided a summary of the proposed project developed in partnership with the California Department of Public Health's Substance and Addiction Prevention Branch (SAPB). He explained that legalization of adult cannabis use had increased youth exposure and reduced perceived risk, creating a need for a statewide prevention and education campaign. The study aimed to understand attitudes, perceptions, and communication needs among teens, young adults, and parents or caregivers to inform future prevention messaging.

The PI explained that phase one of the study would include three age groups: teens ages 13–17, young adults ages 18–20, and parents or caregivers of children and teens ages 11–17. Recruitment would include English-speaking teens and young adults and English- or Spanish-speaking parents or caregivers, with efforts to ensure demographic and regional diversity across California.

Participation includes an eligibility screener, a short survey, and a 90-minute virtual focus group covering cannabis perceptions, reactions to factual statements and sample advertisements, and, for parents, a review of an educational resource. Focus groups will be audio recorded and privately livestreamed for approved observers, with no video recording. Audio files will be transcribed, de-identified, and deleted within one year. Data used for analysis will rely only on participant ID numbers, with identifying information stored separately. Parental permission and youth assent are required.

The Primary Reviewer of the project, Ms. Lund, noted that the application had improved and that many earlier comments had been addressed, but she raised two unresolved issues: the amount of the incentives for the two participant groups and the retention of screener data prior to informed consent. The committee discussed the proposed $125 incentive for teens ages 13-17 and for young adults ages 18-20. Ms. Lund expressed concern that $125 could represent undue influence for minors and recommended lowering the amount for the teen and young adult groups.

The Committee also discussed the screener survey. Ms. Lund noted that the screener collects demographic information not directly tied to eligibility and asked how those data would be used. She explained that if demographic information is used to balance groups, it becomes inclusion and exclusion criteria and must be described in the protocol. The PI responded that demographic and social variables are collected to ensure the focus groups represent California populations, including those more at risk for cannabis use, and admitted that demographic quotas were not included in the protocol but agreed to clarify this in the protocol. The PI clarified that no one would be excluded solely based on race or ethnicity, but that a combination of factors—race, ethnicity, cannabis use, risk perception, and geographic location—would be used to create balanced groups. Ms. Lund emphasized that these criteria must be documented in the protocol.

Ms. Lund then raised concerns about collecting screener information before informed consent and the request to retain that data. She explained that normally such information is asked in the check-in survey, which occurs

after consent, and suggested re-asking the questions at that stage. The PI responded that retaining screener data is possible in human subjects' behavioral studies if participants are informed at the start, if they consent to retention in the permission/assent forms, and if the Institutional Review Board (IRB) approves. The PI recommended keeping the data to reduce participant burden.

The Committee asked whether participants are clearly advised of this option from the beginning, and the PI confirmed they are, with checkboxes in the consent and assent forms allowing participants to agree to aggregate reporting of screener data. He also confirmed that all participants who are found ineligible, their screener data will be deleted, and the data is only retained for participants who agree, are eligible, and complete all study activities. The Committee asked if screener data is linked to individual survey responses. The PI explained that eligible participants are assigned a unique participant ID, and names collected in consent or assent forms are stored separately from survey and focus group data.

The Committee asked if the study would be translated into Spanish. The PI confirmed that two of six parent/caregiver focus groups will be conducted in Spanish to better inform campaign messaging. He explained that the screener asks whether English is a primary or secondary language, or if participants speak English alongside another language, but does not ask for specific languages beyond Spanish.

Controverted Issue – Compensation:

The Committee engaged in significant discussion regarding whether proposed incentive amounts could constitute undue influence. The study originally suggested $125 incentives for all three groups (teens, young adults, and parents/caregivers). A committee member expressed concern that $125 for teens (ages 13–17) and $125 for young adults (ages 18–20) were excessive, recommending lower amounts ($40–50 for teens and reduced amounts for young adults). The PI cited prior CPHS approvals and literature suggesting incentives do not drive undue influence as much as perceived study risk. The Committee acknowledged that incentives are not reimbursements but must be judged for undue influence. Committee members debated whether the incentive amount should differ by age group and whether the proposed amount could influence a teen's decision to assent. Members also discussed whether parents should receive part of the incentive or whether the amount should be reduced across all groups. During discussion, the PI accepted lowering the incentive for teens to $75, before later agreeing to reduce further to $40 in response to Committee concerns. Motions were made to approve with $75 for teens, which failed.
Subsequently, a motion was made to table the project to the February meeting, which passed. The PI then proposed revised incentives ($40 for teens, $75 for young adults, $125 for parents/caregivers) and agreed to add anonymized language to screener data collection. A final motion was made by Ms. Lund and seconded by Dr. Ventura to grant deferred approval, minimal risk, for one year with stipulations: approval limited to Phase One; incentives set at $40 for teens and $75 for young adults, subject to expedited review if adjustments are needed; anonymized language added prior to screener data collection; and review by a subcommittee led by the primary reviewer of the study. This motion replaced the earlier motion to table project #2025-178.

Final Motion: Ms. Lund moved, and Dr. Ventura seconded to grant deferred approval, minimal risk, for one year, with the following specified stipulations which require expedited review and approval by a CPHS subcommittee of Ms. Lund:

Approval is limited to Phase One of the study.

Participant incentives will be adjusted as follows:
Ages 13–17: $40
Ages 18–20: $75

These amounts may be revised through expedited review if evidence indicates they are not effective.

Anonymized language must be included prior to screener data collection.

Approve: Ms. Lund, Dr. Ventura, Dr. Azizian, Dr. Lang, Dr. Palacio, Dr. Schaeuble, Dr. Tefera.

Oppose: None.
Abstain: Dr. Hess.
Absent: Dr. Ruiz, Dr. Johnson, Dr. Dinis.
Total=8 In Favor-7, Opposed-0, Abstained-1
For the record, this motion replaces the prior motion to table Project #2025-178.

4) Project #:	**2025-180 (Dickey)**
Title:	Child Care Policy Research Partnerships – Professional Development as a Strategy for Improving Access to Quality Child Care for Young Dual Language Learners in California
PI:	Dr. Kitmitto
Board Decision:	Approval, minimal risk

Discussion:
The Principal Investigator (PI) from the American Institutes for Research (AIR) introduced the study team and presented a summary of the project. The project is a partnership between AIR and the California Department of Social Services (CDSS), funded by the federal Administration for Children and Families. The study aims to examine professional development as a strategy to improve access to quality childcare for young dual language learners in California.

The PI explained that two of the four project tasks require access to restricted CDSS data, including de-identified 801A subsidy data and new dual language learner data collected under Assembly Bill (AB) 393. The first task will describe the distribution and characteristics of dual language learners in the subsidized childcare system using de-identified administrative data. The second task will survey childcare center directors and family childcare homeowners who receive CDSS subsidies to assess access to and use of dual language learner-focused professional development.

The primary reviewer, Dr. Dickey, clarified that because CDSS data would be used to obtain provider contact information, the project requires review under the federal Common Rule rather than solely under the Information Practices Act (IPA). The Committee discussed that the unit of analysis is the provider or program rather than individual children, and that the survey questions are program-focused and not sensitive.

The PI described data security procedures, including use of de-identified administrative data, separation of contact information from survey responses, secure storage, and reporting only aggregate results with suppression of small cell sizes to reduce re-identification risk. The Committee agreed that the project presents minimal risk to participants.

Motion: Dr. Hess moved, and Dr. Teferra seconded to approve the project as submitted for a period of one year, classified as minimal risk.

Approve: Dr. Hess, Dr. Teferra, Dr. Azizian, Ms. Lund, Dr. Lang, Dr. Palacio, Dr. Schaeuble, Dr. Tefera, Dr. Ventura.
Oppose: None.
Abstain: None.
Absent: Dr. Ruiz, Dr. Johnson, Dr. Dinis
Total=8 In Favor-8, Opposed-0, Abstained-0

G. Full Board Continuing Review
None.

H. Amendments – Full Committee Review Required
None.

I. Second Review Calendar

None.

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 (3)

K. 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 (97)

K1. 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 (32)

L. Amendments – Projects with Revisions Approves 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 (20)

M. Projects with Request for CPHS to Rely on Another IRB
None.

N. Exemption/Not Research Approvals
Total Project Count (27)

O. Final Reports
Total Project Count (7)

P. Public Comments
None.

Q. Next Meeting
The next CPHS meeting is scheduled to be held on Friday, February 6, 2026.

R. Adjournment
This meeting was adjourned at 12:40 PM on December 5, 2025.