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

Remote Attendees
Laura Lund, MA
Maria Dinis, PhD, MSW

Alternate Member
Millard Murphy, JD
Lois Lowe, PhD

Friday, August 1, 2025
8:30 a.m.

Zoom:
CPHS August 1, 2025, Full Committee Meeting

Meeting ID: 160 350 3956
Passcode: 708307

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

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Meeting ID: 160 350 3956

MINUTES

CDII
John Ohanian, Director
Agnieszka Rykaczewska, Deputy Director

CPHS Administrator
Agnieszka Rykaczewska

Committee Members Present in Person:
Catherine Hess, PhD
Larry Dickey, MD, MPH
Carrie Kurtural, JD
John Schaeuble, PhD, MS
Jonni Johnson, PhD
Maria Ventura, PhD

Committee Members Present Remotely:
Maria Dinis, PhD, MSW
Laura Lund, MA

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

CalHHS Present Remotely:
Maggie Schuster

OTSI Staff In person:
Deanne Wertin
Mark Owens

Also, Present Principal Investigators and Associate Investigators Remotely:
Sibylla Leon Guerrero
Sunny Lowell
David Lang
Lemeneh Tefera
Ella Star
Ashish Deshmukh
Alina Xu
Angelique Lastinger
Christopher Anderson
Kelsey Pukelis
Laura Carper
Joshua Fedewa
Cheryl Byers

A. Welcome

a) Chair Updates
Dr. Hess called the meeting to order and reminded remote participants to keep their cameras on during the meeting. Sussan Atifeh took roll, established quorum, and noted that Dr. Azizian, Dr. Ruiz, and Dr. Palacio would be absent for this meeting. Dr. Dinis joined the meeting five minutes late during the Chair updates.
Dr. Hess informed the board that last week the California Health and Human Services (CalHHS) Secretary appointed two new board members. The new members are present at today's

meeting via Zoom and will introduce themselves to the committee. Both will be officially sworn into CPHS during the October 3, 2025, meeting.

Dr. Hess provided Dr. David Lang's background to the committee. Dr. Lang is currently the research manager at the Cradle-to-Career California Program and a postdoctoral research fellow at Stanford. He leads the development and maintenance of a longitudinal data system linking K–12, post-secondary, workforce, and other life outcome data. Dr. Lang has extensive experience with data governance and has led large-scale research studies on the impacts of educational policies. He also has experience working with sensitive populations, including children, individuals with disabilities, and students eligible for free or reduced-price lunches.

Dr. Hess introduced the second new board member joining CPHS, Dr. Lemeneh Tefera. Dr. Tefera currently serves as the Chief Medical Officer and Deputy Director of Clinical Innovation at the Department of Health Care Access and Information (HCAI). He is also a practicing emergency medicine physician with over 25 years of clinical experience. Dr. Tefera has held multiple faculty appointments and has been part of several clinical research teams. He also served as Senior Advisor and Medical Officer at the Centers for Medicare and Medicaid Services, shaping policies that promoted patient safety and hospital quality improvement. His expertise in research related to healthcare affordability, behavioral health, economics, and emergency medicine will contribute to the diverse healthcare research studies submitted to CPHS.

There were no questions from any committee members or the public regarding this agenda topic.

B. Administrative Update

a) Share CDII update and introduction to new CPHS consultants

Dr. Agnieszka Rykaczewska, the CPHS administrator, informed the committee that the Center for Data Insight and Innovations (CDII) Director, John Ohanian, will be transferring out of his role starting today, August 1st, 2025. As part of the transition, CPHS will be transferred to the Office of Technology and Solutions Integration (OTSI). CDII and OTSI has worked closely together over the past serval years, most recently on the IT and data strategic plan.

Dr. Rykaczewska introduced Deanne Wertin, who serves as OTSI's Chief Deputy Director and Deputy Agency Information Officer, along with Mark Owens, OTSI's Chief Counsel.

Ms. Wertin informed the committee that, as of August 1, 2025, CDII had officially joined OTSI. She assured the committee that during this transition, no immediate changes would occur, and all staff would remain in their current roles.

Ms. Wertin also provided background on OTSI and explained why this alignment is a strong fit for CPHS. Formerly known as OSI, OTSI underwent a name change a few years ago. The department was established 25 years ago to plan and deliver complex and critical information technology (IT) solutions for California Health and Human Services (CalHHS). Over the years, OTSI has led and continues to manage major initiatives such as the California Healthcare Eligibility, Enrollment, and Retention System (CalHEERS), the Electronic Benefit Transfer (EBT) project, and the Child Welfare Services/Case Management System (CWS/CMS), among others.

These systems handle sensitive data across various departments and sponsors. OTSI's primary responsibility is to ensure data security and privacy protections are in place. The department includes both an Agency Information Security Officer and an Information Security Officer dedicated to safeguarding the systems and the data they process. While sponsors retain ownership of their data, OTSI manages the systems on their behalf, working closely with them to ensure robust protection measures are implemented.

In the past three years, OTSI has expanded its scope to include internal consulting services. This newer function supports departments in identifying and building data architecture, leveraging the same expertise used in large-scale projects. The goal is to help departments develop secure, well-structured systems that uphold data integrity and privacy.

In March 2024, OTSI published the IT and Data Strategic Plan in partnership with the Center for Data Insights and Innovation (CDII). This plan outlines a vision for a future built around person-centered services that are interconnected and responsive. It emphasizes the importance of understanding individuals' needs, meeting those needs effectively, and using insights gained throughout the process to inform and improve departmental policies.

Ms. Wertin opened the floor for questions. In response, Ms. Kurtural asked who would be serving as legal counsel for CPHS. Ms. Wertin confirmed that Maggie Schuster would continue to support CPHS, alongside Mark Owens, OTSI's Chief Counsel.

Mark Owens introduced himself to the committee, noting that he has been practicing law for 30 years and has built a team of seven attorneys whose philosophy centers on accessibility and service. He expressed his commitment to CPHS by assuring the committee that both he and his team are available at any time to support their needs.

Dr. Rykaczewska reminded the committee that in the last meeting she noted that, in order to align with best practices, CPHS is seeking to review its policies and procedures to ensure they are up to date. In support of this, CPHS has sought procurement services from experts in the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), and human subjects research to assist with the review. The intention is for the consultants to make recommendations to the board, followed by review by the Secretary. Dr. Rykaczewska acknowledged Dr. Hess and Dr. Dickeys, who served as the review board. The consulting service chosen to assist CPHS was Advarra Consulting Services.

Dr. Rykaczewska introduced the Advarra team: Joshua Fedewa, Cheryl Byers, and Corinna Cuevas. Mr. Fedewa then introduced himself to the committee, sharing that he has served as Advarra's Director of Consulting for the past year. Prior to joining Advarra, he held director roles at two major academic institutions, one in Texas and one in Michigan, and has spent the past 15 years working with institutions on regulatory matters.

Mr. Fedewa expressed enthusiasm about collaborating with CPHS, particularly in assessing current policies and procedures, identifying areas for increased efficiency, and strengthening compliance measures.

Cheryl Byers introduced herself to the committee, sharing that she serves as the Senior Vice President of Advarra Consulting. She has worked in research compliance and administrative roles for the past 26 years and expressed enthusiasm about supporting the project.

Dr. Rykaczewska thanked both Mr. Fedewa and Ms. Byers for their introductions. She noted that discussions regarding the project approach are still in the early stages and that updates will be shared in future committee meetings.

Dr. Rykaczewska then opened the floor for questions from both the committee and the public. No questions were raised by either group.

C. Review and Approve of Meeting Minutes

Dr. Hess asked if there were any committee comments or public comments on the meeting minutes from the April 5, 2025, Full Board Meeting.

No committee or public comments were made.

Motion: It was moved by Dr. Johnson and seconded by Dr. Dickey to approve the April 5, 2025, Full Board Committee Meeting Minutes.

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

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

Dr. Hess asked if there were any committee or public comments on the meeting minutes from the June 6, 2025, Full Board Committee Meeting. Dr. Rykaczewska noted that the revised version of the meeting minutes had been sent to the committee, incorporating the changes recommended by Dr. Schaeuble.

No committee or public comments were made.

Motion: It was moved by Ms. Kurtural and seconded by Dr. Dickey to approve the June 6, 2025, Full Committee Meeting Minutes.

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

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

D. Projects with Reported Adverse Events and/or Deviations

None.

E. New Projects – Full Committee Review Required

1. Project #	2025-067 (Johnson)
Title:	Types of Infant Formula and Infant Outcomes
PI:	Christopher Anderson, PhD, MSPH
Co-PI:	Shannon Whaley, PhD
Board Decision:	Approved Pending Conditions - Designee Review

Discussion:

Ms. Lund recused herself from the discussion due to a conflict of interest (COI).

This project was discussed in the CPHS June 2025 full board meeting and was tabled to the August 2025 full board meeting. The board discussed the revised study from PHEF/WIC (Public Health Foundation Enterprises/Women, Infants, and Children). Dr. Johnson, the primary reviewer, introduced the study and noted that changes had been made since the last discussion in June. Dr. Anderson, the Principal Investigator (PI) of the project explained that the study protocol had been simplified dure to changes in the California WIC infant formula contract, which also took effect on August 1st, 2025. In response to the statewide switch from one infant formula manufacturer to another, PHFE WIC implemented two new policies related to infant formula issuance. The first policy sets lactose-based infant formula as the default option in the first month unless there is a medical reason for using a non-lactose formula. Mothers may choose to switch to a glucose-based formula beginning the second month if they prefer. The second policy involved training WIC staff on these changes. Dr. Anderson stated that the study aims to ensure that infants, especially those not fully breastfed receive adequate nutrition during their first year. The study seeks to evaluate whether these new policies result in increased use of lactose-based formulas and decreased use of glucose-based alternatives. To do this, researchers plan to collect data from PHFE WIC-Participating mothers when their infants are around 3 months and 9 months old. These time points were chosen to evaluate feeding practices before and after the introduction of complementary foods and beverages. The goal is to determine whether the policy changes lead to healthier diets and reduction in rapid infant weight gain, which is a known risk factor for childhood obesity. Dr. Anderson noted that the 3-month survey will be brief and should take no more than 30 minutes. The 9-month survey will be more detailed and includes a 24-hour dietary recall to better capture the infant's intake of solid foods and beverages at that stage.

Dr. Johnson reviewed the minutes from the previous meeting and confirmed that the consent form had been updated to clearly state that the primary purpose of the study was to evaluate changes in the infant formula being issued to participants. She added that the consent form now outlines the timing of the policy change and how it connects to the study. The research team also included instructions on how participants can access more detailed information if they wish to learn more, and they would be provided with contact information to seek additional details about the study as part of the recruitment and consent processes.

Dr. Johnson confirmed that the required additions had been made to the study procedures earlier that week. She also noted that previous concerns regarding the use of measurement cards were no longer relevant, as the cards had been removed from the protocol. Additionally, she acknowledged that the research team had made several improvements. These included adding instructions to the survey about the option to skip questions, improving transparency in recruitment materials, and clearly explaining who the researchers are and why they are contacting participants. Participants now also have the option to decline future contact for research purposes without affecting their participation in the WIC program.

Dr. Johnson expressed satisfaction with the updated consent materials and overall changes. The Spanish versions of the consent and recruitment forms were still pending review by Dr. Ruiz.

Motion: Dr. Johnson moved, and Dr. Dickey seconded, to grant a deferred approval, for one year under minimal risk pending the following specified minor revision which require expedited review and approval by a CPHS subcommittee of Dr. Johnson.

—Please obtain and attach the Spanish-translated materials designated for Dr. Ruiz's review.

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

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

2. Project #	2025-068 (Ventura)
Title:	Understanding Enrollment in Public Benefit Programs: Evidence from Disaster Supplemental Nutrition Assistance Program (D-SNAP) and SNAP
PI:	Kelsey Pukelis, PhD
Co-PI:	Laura Carper, PhD
Board Decision:	No Purview

Discussion:

This project was discussed in the CPHS June 6, 2025, full board meeting and was tabled to the August 1, 2025, full board meeting.

Dr. Pukelis provided an overview of the project, which aimed to study the impact of disaster food assistance programs such as Disaster Supplemental Nutrition Assistance Program (D-SNAP) and SNAP in California, focusing on participant experiences and enrollment barriers. The study included interviews and field observations. She clarified that the project was conducted as part of her Harvard fellowship, not in her capacity as the California Department of Social Services (CDSS) employee.

She addressed three main revisions in response to previous comments: (1) expanding the participant pool to include Spanish-speaking individuals, (2) clarifying her institutional affiliation with a forthcoming Memorandum of Understanding (MOU) stating that all data would be housed and secured by Harvard, and (3) updating the consent forms to include the Institutional Review Board (IRB) contact information and clarify that participation would not affect benefit eligibility. Dr. Ventura, the Primary reviewer of the project clarified that in a meeting she and CPHS administrator, Dr. Rykaczewska, had consulted with CDSS's Information Security Office (ISO) and it was confirmed that the data would be stored exclusively in the Harvard University under Harvard's protocols and the data would not be managed or accessed through CDSS systems. Based on this clarification, Dr. Ventura mentioned that the data would be entirely under Harvard's control and questioned CPHS' purview over the project.

Dr. Pukelis mentioned that there was no formal request from CDSS for CPHS to act as the IRB

of record, and the project had already undergone IRB review at Harvard University. Given that, board members expressed concern about reviewing a project managed by an outside institution and the board concluded that the study did not fall under CPHS purview. Dr. Pukelis was advised that if the project changes in scope such as involving CDSS data or conducting research in her capacity as a CDSS employee, she should submit the project application to CPHS for review and approval.

Motion: Dr. Ventura moved, and Dr. Dickey seconded to confirm that the project is not under CPHS' purview and CPHS will not be reviewing this protocol.

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

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

F. Full Board Continuing Review
None.

G. Amendments – Full Committee Review Required

1. Project #	2024-183 (Lund)
Title:	Priorities, Preferences, and Tradeoffs Among Older Adults with Oropharyngeal Cancer
PI:	Evan Graboyes, MD, MPH
Co-PI:	Ashish Deshmukh, PhD, MPH
Board Decision:	Approved

Discussion:

Ms. Lund informed the committee that she had recommended this amendment be reviewed by the full committee, as the researchers were requesting significant changes to human subjects aspects of the protocol. Ms. Lund had prior questions regarding the amendment, but the researchers resolved those, and she no longer had concerns or questions.

Ms. Lund turned it over to the Co-PI of the project, Dr. Ashish Deshmukh, to describe the changes being requested in the amendment. Dr. Deshmukh prepared a PowerPoint presentation that was displayed over Zoom to the committee.

Dr. Deshmukh provided context regarding the project. He and the PI, Dr. Evan Graboyes, have received a grant from the National Cancer Institute to optimize treatment for Human Papillomavirus-Associated Oropharyngeal Cancer in older adults in the United States.

Dr. Deshmukh mentioned that HPV-associated Oropharyngeal Cancer has been recognized as the fastest rising cause of cancer, now more common than Cervical Cancer.

The overall goal of the project is to reduce treatment toxicity while maintaining survival benefits for patients. The research team will aim to measure what is most important to patients in terms

of treatment priorities and preferences. The objective of the study is to measure patient-centered outcomes that are critical to informing preference, concordance, and decision-making.

Dr. Deshmukh summarized the amendment. The research team is proposing to add two new baseline assessments for participants to complete: EQ-5D-5L (EuroQol 5-Dimension 5-Level) and MDASI-HN (MD Anderson Symptom Inventory – Head and Neck Module). Changes to the study procedures include audio-recording and screen-recording the teleconference visit for quality assurance, and having participants complete the MDASI-HN and EQ-5D-5L as baseline study assessments.

The consent form and script methods have been updated to reflect the requested amendments.

Dr. Deshmukh explained that the EQ-5D-5L is a validated measure of health status and health-related quality of life, comprising five dimensions: Mobility, Self-care, Usual Activities, Pain/Discomfort, and Anxiety/Depression. Each dimension has five response levels of severity: no problems, slight problems, moderate problems, severe problems, and unable to/extreme problems.

The MD Anderson Symptom Inventory – Head and Neck (MDASI-HN) is a cancer-specific validated inventory tool used to measure perceived severity, frequency, and impact of head and neck cancer-related symptoms. Higher scores indicate greater severity and frequency of symptom interference.

Dr. Deshmukh asked if the committee had any questions. Dr. Johnson asked for more detail about the quality assurance plans for the recordings. Dr. Deshmukh explained that quality assurance is intended to measure utility scores using the standard gamble method. To prevent human error, the research team will record the survey capture. During interactions with patients, the research team will verbally ask for permission to record the session. If patients decline, the session will not be recorded.

There were no public comments. Dr. Rykaczewska requested that the research team send the presentation so the slides can be posted on the CPHS website.

Motion: It was moved by Ms. Lund and seconded by Dr. Johnson to approve the amendment with minimal risk and the existing timelines of this study.

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

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

2. Project #	2025-004 (Johnson)
Title:	valuation of Community Response Initiative to Strengthen Emergency Systems (C.R.I.S.E.S) Act Grant Program
PI:	Catherine Dun Rappaport, MPP
Co-PI:	Alina Xu, MBA/MPA
Board Decision:	Tabled

Discussion:

Dr. Johnson provided context to the committee regarding the project under discussion. The project was previously approved earlier this year and focuses on alternative responders to police encounters involving people in crisis. Dr. Johnson mentioned that a new procedure had been proposed for administering in-person and virtual interviews with individuals who had previously received services and completed surveys. She brought the new consenting procedures to the full board for review.

Dr. Johnson asked Dr. Alina Xu to summarize the changes being requested for the protocol. Dr. Xu explained that the amendment focuses on adding a procedure for client interviews. The research team would select clients for follow-up interviews based on their responses to the client satisfaction survey. The survey includes a question asking clients if they are willing to be contacted for a follow-up interview to provide more insight into their experiences receiving alternative crisis response services. If they agree to be contacted, they will provide their name, email address, and phone number.

Dr. Johnson suggested allowing participants to preview the interview questions during the consent process. This would provide a buffer period between when participants are consented and when they are interviewed, allowing them time to consider whether they wish to discuss the traumatic event in more detail with the research team.

Dr. Xu confirmed that she could include a preview of the types of questions participants would be asked and noted that there would be two interviewers present during the interview.

Dr. Johnson expressed satisfaction with the researchers' decision to update the consent form to include a preview of questions. She also recommended reiterating to participants at the time of the interview that if they do not feel comfortable answering any questions, they are permitted to skip them or end the interview.

Dr. Johnson brought up that after the interview is completed, the transcripts are uploaded to the Dovetail program. Dovetail is a qualitative analysis software used to analyze transcripts. However, Dovetail is not a HIPAA-compliant software. Dr. Johnson asked whether Dovetail has the ability to generate audit trails or if it would have access to use the transcripts for its own purposes.

Dr. Xu is exploring alternative tools and appreciated Dr. Johnson flagging that Dovetail is not HIPAA-compliant. The team is researching Deduce, which has similar functionality to Dovetail in terms of qualitative data analysis and is HIPAA-compliant with better data security. Once the research team finalizes their decision, they will share with Dr. Johnson which tool they will be using and the measures the platform takes to protect data.

Dr. Xu noted that if they proceed with a software like Dovetail, the research team will go through a process of scrubbing the interview data to ensure it does not contain HIPAA identifiers. However, the team's preference is to use a platform that is HIPAA-compliant to avoid the manual step of data scrubbing, which remains prone to human error.

Dr. Hess asked whether these are cloud-based services, as the board might have concerns about potentially sensitive information being uploaded to a cloud hosted by a third-party platform.

Ms. Lund suggested that since the work is being conducted under contract with CDSS, the research team might have access to CDSS's confidential data storage and data uploading protocols.

Dr. Dickey suggested that the issue is not data storage, but rather the use of an analysis tool like AI.

Dr. Xu informed Ms. Lund that all other data generated throughout the study will be stored on the CDSS SharePoint server.

No public comments were made.

Motion: **It was moved by Dr. Johnson and seconded Dr. Dickey by to approve the Spanish consents and the additional fields to the survey, minimal risk with the existing timeline approval. Motion to table the decision to for approval of the interview analysis software to be used.**

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

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

H. Second Review Calendar

Some projects listed may have been approved by expedited review prior to this meeting and were not reviewed by the full committee.
Total Project Count (2)

I. New Projects – Expedited Review Requested
Some projects listed may have been approved by expedited review prior to this meeting and were not reviewed by the full committee.
Total Project Count (19)

J. 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 (100)

J1. 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 (25)

K. 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 (14)

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

M. Exemption/Not Research Approvals
Total Project Count (8)

N. Final Reports
Total Project Count (8)

O. Public Comments
None.

P. Next Meeting
The next CPHS meeting is scheduled to be held on Friday, October 3, 2025.

Q. Adjournment
This meeting was adjourned at 10:21 AM on August 1, 2025.