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
Philip Palacio, EdD, MS
Juan Ruiz, MD, DrPH, MPH
Laura Lund, MA

Alternate Member
Millard Murphy, JD
Lois Lowe, PhD

Friday, June 6, 2025
8:30 a.m.

Zoom:
CPHS June 6, 2025, Full Committee Meeting

Meeting ID: 161 492 8396
Passcode: 107500

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

Phone:
+1 669 254 5252 US (San Jose)
+1 669 216 1590 US (San Jose)
+1 646 828 7666 US (New York)

Meeting ID: 161 492 8396

CDII
John Ohanian, Director
Agnieszka Rykaczewska, Deputy Director

CPHS Administrator
Agnieszka Rykaczewska

MINUTES

Committee Members Present in Person:

Catherine Hess, PhD
Larry Dickey, MD, MPH
Allen Azizian, PhD
John Schaeuble, PhD, MS
Jonni Johnson, PhD
Carrie Kurtural, JD

Committee Members Present Remotely:

Philip Palacio, EdD, MS
Juan Ruiz, MD, DrPh, MPH
Laura Lund, MA

CPHS Staff Present in Person:

Agnieszka Rykaczewska, PhD
Sussan Atifeh
Karima Muhammad
Nicholas Zadrozna

Cal HHS Present Remotely:

Jared Goldman
Maggie Schuster
Francis Brown

Principal Investigators and Associate Investigators In person:

Michael Valle
Jame Yi
Chris Krawczyk

Also, Present Principal Investigators and Associate Investigators Remotely:

Chelsea Austin
Abigail Ramirez
Ivonne Romero
Kathryn Conlon
Alma Torres-Nguyen
Evan White
Regan Foust
Christopher Anderson
Olivia Burdon
Kelsey Pukelis
Laura Carper
Dan Friend
Haley McCrary
Angelique Lastinger
Joelle Atere- Roberts
Jenn Gordon
Dana Peterson
Chris Craig
Adrian Aryarad
Wade Luele
Dionne Evans- Dean

Scott Christman

A. Welcome

a) Chair Updates

Dr. Hess called the meeting to order and reminded remote attending participants to keep their cameras on during the meeting. Sussan Atifeh took roll and established quorum and noted that Dr. Ventura and Dr. Dinis will be absent for this meeting.

Dr. Hess informed the committee that she was requested to not have discussions about the subcommittee work at this time and there are no updates to share.

B. Administrative Update

Dr. Rykaczewska, CPHS Administrator, had several updated to provide to the committee. Dr. Rykaczewska provided an updated on the recruitment for CPHS. She reminded the committee that there are two openings on the board at this time. CPHS has received four applications from candidates to join the committee. The applications are currently being reviewed with the Chair and Vice Chair. Once the applications are reviewed, the next steps would be for the Chair to provide a prioritized list of the candidates to the California Health and Human Services (CalHHS) secretary who would then appoint the members.

Dr. Rykaczewska updated the committee regarding the adverse event that was discussed in the April full board meeting. During the April meeting a motion was passed, and part of that motion was to notify the Chief Information Security Officer (ISO) at University of California San Francisco (UCSF) and ask them to investigate whether there was a security breach, and whether any personal identifiable information was exposed. Dr. Rykaczewska received an update earlier this week from the Chief ISO and they have concluded their investigation. They reported that the data was encrypted and found no indication of unauthorized access. The UCSF ISO has submitted a report to Dr. Rykaczewska marked as confidential. Dr. Rykaczewska asked if anyone has any future questions regarding the adverse event to reach out directly to her.

Dr. Rykaczewska last update is related to the review of the CPHS Policies and Procedures. To be in alignment with best practices CPHS administrative team seeking to do a review of the Policies and Procedures (P&P) to make sure they are up to date and align with any regulatory changes and reflect the best practices. To support these efforts, CPHS administrative team is seeking procurement of consultation services from experts in the Office for Human Research Protections (OHRP), U.S. Food and Drug Administration (FDA), and state human subjects research regulations, and who have experience in IRB administrative and operating procedures. The intention is to have the consultants review the CPHS Policies and Procedures, and another supporting documents to make recommendations to the Board and for the CalHHS Secretary's review and considerations. The consultant's recommendations would come back to the full board for discussion of the suggestions and recommendations.

CPHS administrative team also sought out a consultant that is an expert in Artificial Intelligence (AI) and data security. However, there was no luck in identifying a consultant that met those meets or have the experience and expertise. CPHS administrative team will discuss different strategies of procuring the AI and data security consultants and try with the new approach.

C. Review and Approve of Meeting Minutes

Dr. Hess asked if there were any comments or public comments on the meeting minutes from January 10th Sub-Committee.

No comments or public comments were made.

Motion: It was moved by Dr. Azizian and seconded by Dr. Johnson to approve the January 10th Sub-Committee Meeting Minutes.

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

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

Dr. Hess asked if there were any comments or public comments on the meeting minutes from March 7th Full Board Meeting.

No comments or public comments were made.

Motion: It was moved by Ms. Kurtural and seconded by Dr. Johnson to approve the March 7, 2025, Committee Meeting Minutes

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

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

D. Projects with Reported Adverse Events and/or Deviations

None.

E. New Projects – Full Committee Review Required

1. Project # 2024-067 (Johnson)
   Title: Types Of Infant Formula and Infant Outcomes
   PI: Christopher Anderson, PhD, MSPH
   Board Decision: Tabled to August 1st, 2025, Full Board Meeting

Discussion:

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

The study led by Dr. Christopher Anderson from PHEF/WIC (Public Health Foundation Enterprises/Women, Infants, and Children), aims to assess how a change in infant formula

affects WIC recipients. The research will compare outcomes before and after the formula switch.

A Component involving WIC staff was removed and will be reviewed separately. The current review focuses only on human subject's contacts of WIC participants.

Dr. Johnson, the primary reviewer, noted that the research team still has unresolved issues and requested feedback from the board.

WIC provides infant formula to babies whose mothers cannot breastfeed. California's WIC formula contract was last updated in August 2022. PHEF/WIC plans to change the default formula for infants under one month to a lactose-reduced version (unless a specialty formula is needed). This change is based on evidence linking added corn syrup solids in formula to higher obesity risk. PHFE/WIC will provide additional staff training before the policy is implemented.

The State WIC agency is changing infant formula manufacturers in August 2025, which is earlier than expected. As a result, the research team submitted this proposal to CPHS earlier than planned. The study aims to collect survey data from caregivers of infants at 3 months old and 9 months old. The surveys will include brief questionnaires, and dietary recalls assessing what the infant consumed in the last 24 hours. Also, they collect anthropometric data (length and weight) which participants can either get measured at WIC sites or by having their healthcare provider fill out a card and return it by mail. The team is working under a tight timeline due to the formula change being moved up.

Dr. Johnson mentioned that the consent form lacks clarity, It does not mention the formula change and it does not state whether participants are notified about this change.

Dr. Anderson stated that the team is not allowed by CDPH/WIC (California Department of Public Health/Women, Infants, Children) to notify participants about the formula policy change. The CPHS WIC program wants to handle communication with participants themselves. The research team is willing to adjust language in the consent form but must first get clearance from CDPH WIC to avoid interfering with WIC's messaging or operations.

Dr. Johnson emphasized the need for transparency in the consent form. She noted that the current language does not clearly explain the change in formula and its potential impact on infants. She found it troubling that participants might not be fully aware of what is changing, especially for newborns. She asked Dr. Anderson whether there are procedures in place to identify if a parent has lost their infant between the time of enrollment and contact. This is to avoid causing distress by inadvertently contacting bereaved parents. Dr. Anderson clarified that if an infant is deceased, it is flagged in WIC programmatic data. Most WIC infants in California are tracked starting in pregnancy and attempts to contact families begin after the expected delivery date.

Dr. Johnson requested this be added to the application, since it was not currently mentioned. She recommended stating that administrative data will be used to avoid contacting bereaved parents. Dr. Johnson also mentioned that Spanish-language materials must be included with the protocol for all surveys and recruitment material and how parent contact information is obtained need to be discussed further. She mentioned, a specific section in the questionnaire asks whether the respondent is the current caregiver and, if not, asks for the current caregiver's contact information. Dr. Johnson inquired how the team plans to handle this information.

Dr. Anderson explained they typically contact the current caregiver when doing population-based recruitment for WIC studies. He referenced prior data showing this method is reliable,

with only 3 non-custodial individuals out of over 6,700 in a previous survey. The administrative data is regularly updated and reflects the current caregiver receiving WIC benefits.

Dr. Johnson raised ethical concerns about collecting contact information from people not in the study pool. With only 3 out of 6, 000 plus falling into this category, she questioned the need to include that language. She said it is fine to confirm who the caregiver is, but not to proceed if it is someone outside the pool.

Dr. Anderson responded that it is a negligible proportion, and he is open to removing that language, suggesting instead a message like "Sorry you are not eligible."

Dr. Johnson said her remaining issues in IRBManager relate to procedural inconsistencies and redundancy with administrative data, but these could be resolved though back-and-forth.

Dr. Hess recommended revisiting the consent and expressed concern about approving a consent form that omits the study's reason and suggested they may need to push back at CDPH.

Dr. Dickey asked why CDPH does not want to disclose the formula change. Dr. Anderson clarified that CDPH is not trying to hide the information but wants to avoid confusion among WIC participants. Starting in August, CDPH will begin providing different contact infant formulas and wants to handle all communications about this directly. They have asked that researchers delay any data collection or communication until after the change goes into effect so that their messaging is not disrupted. Dr. Anderson added that once the formula change takes place on August 1st, the study can proceed, since participants will already be aware of the new formula. Ms. Kurtural asked if the new supplier contact is currently active, and Dr. Anderson confirmed that it will go into effect in August. Ms. Kurtural agreed it makes sense to delay communication until then and suggested updating the consent form in August. She recommended tabling the project until the August 1st full board meeting, when the researchers can return with the revised materials.

Motion: It was moved by Dr. Johnson and seconded by Dr. Dickey to table the project to the CPHS August 1st, 2025, full board meeting. During this time, Dr. Anderson, the principal investigator of the project will work with CDPH to develop language on the consent form to increase transparency about what the study is about and work with Dr. Johnson the Primary reviewer of the study to address the remaining issues.

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

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

2. Project # 2024-068 (Azizian)
   Title: Understanding Enrollment in Public Benefit Programs: Evidence from Disaster Supplemental Nutrition Assistance Program (D-SNAP) and SNAP
   PI: Kelsey Pukelis, PhD
   Board Decision: Tabled to August 1st, 2025, Full Board Meeting

Discussion:

Dr. Azizian the Primary reviewer of the project opened the discussion by congratulating Dr. Pukelis on earning her PhD. He noted that the study focuses on eligibility and participation in Disaster Supplemental Nutrition Assistance Program (D-SNAP) which provides food assistance during disasters. Dr. Pukelis gave an overview, explaining the study aims to understand experiences of applying for and using disaster food aid, challenges like stigma or lack of awareness, and how disaster program use may influence future SNAP use. They will use interviews and field observations, including visiting D-SNAP application sites and possibly taking photos (with faces blurred). Participants include applicants and administrators. Risks include possible discomfort during interviews or confidentiality concerns. The team plans to protect privacy by making interviews optional and private, allowing participants to skip questions, and not recording personal details in field notes or photos.

Dr. Azizian asked for more details about how participants will be recruited. Dr. Pukelis explained they will contact administrators through her connections to the California Department of Social Services (CDSS) and approach applicants at D-SNAP sites. Interviews can be done on-site or later over Zoom. Participants will receive a $25 gift card; administrators can decline if there is a conflict. Consent will be given verbally using a script. There is also a flyer. If the interview is in person, they can give out a paper copy of the consent information. For remote interviews, an electronic version might be used.

Dr. Dickey requested including language in the consent form clarifying for the participants that their participation does not affect their benefit access and including IRB contact information for participants in case they have questions about their rights.

Dr. Azizian requested considering using a written consent form rather than just verbal, especially for in-person interviews. Dr. Pukelis said she is open to using written consent in person and will think about the best option for remote ones.

Dr. Ruiz asked if the same consent form is used for both groups. Dr. Pukelis mentioned that they are different but similar.

Dr. Dickey questioned about excluding non-English speakers. Dr. Pukelis said eligibility is limited to English speakers for now, since she does not speak Spanish comfortably.
Ms. Lund emphasized that this could be an ethical issue, especially in California where many applicants may speak only Spanish. She suggested the team consider including Spanish speakers to make findings fairer and more inclusive. Dr. Pukelis agreed to explore this.

Dr. Azizian suggested tabling the project until the CPHS August 1st, 2025, full board meeting so the team has time to consider expanding the study to Spanish-speaking participants and address consent form issues. Dr. Pukelis agreed.
No public comments were received.

Motion: It was moved by Dr. Azizian and seconded by Dr. Schaeuble to table decision on this study to the August 1, 2025, meeting.
Approve: Dr. Azizian, Dr. Schaeuble, Dr. Dickey, Dr. Johnson, Ms. Kurtural, Ms. Lund, Dr. Palacio, Dr. Ruiz.
Oppose: None.
Abstain: None.
Absent: Dr. Ventura, Dr. Dinis.
Total=8 In Favor-8, Opposed-0, Abstained-0

3. Project # 2024-066 (Dickey)
Title: Evaluation of the California Children and Youth Behavioral Health Initiative (CYBHI): Caregiver, Youth & Young Adult Focus Groups
PI: Dan Friend, PhD.
Board Decision: Approved Pending Conditions - Designee Review

Discussion:

This project is part of the broader Children and Youth Behavioral Health Initiative (CYBHI) which is funded by the California Health and Human Services Agency (CalHHS). Dr. Dickey explained that the proposal had originally been broad and lacked detail on specific programs and research questions. Since then, the research team has revised the materials to include the names of programs to be evaluated and sample questions related to each.

Researchers explained as part of the large CYBHI evaluation, Mathematica will lead virtual focus groups with youth and caregivers to learn about their experiences with California's behavioral health programs. The study has two primary goals: to assess how participants have benefited from CYBHI-Funded services and to identify any remaining gaps in care. Focus groups will include two groups: youth and young adults ages 14-25, and caregivers of children and youth ages 0-25.

Participants will complete an online screener that gathers demographic information to determine eligibility and group assignment. This screener will be stored on a secure, encrypted server. The protocol was updated to allow youth to complete the screener themselves, just like the young adults and caregivers. For youth under 18, parental consent will be obtained, while those 14-17 will also provide verbal assent. Verbal consent will be collected from participants 18 and older at the start of the focus group. The consent form was revised to describe how participants are identified, the risks and how they will be managed, mandatory reporting rules, voluntary participation, and available crisis resources such as the 988 Suicide and Crisis Lifeline and Substance Abuse and Mental Health Services Administration (SAMHSA). Contact information for the Committee for the Protection of Human Subjects (CPHS) was also added. Each focus group will be 90 minutes and held virtually. Topics will include participant perceptions and experiences with CYBHI programs. The research team plans to offer sessions in Spanish for caregivers who prefer it. At the end of the session, participants will receive a $50 electronic gift card.

Recruitment will be done through community-based organizations (CBOs) funded by CYBHI. These CBOs will share flyers and screener links but will not have access to screener data or attend the focus groups.

To protect participants' well-being, all facilitators will be trained by an in-house mental health professional in trauma-informed and youth-centered methods. Local mental health resources will be customized for each county where focus groups are held. Participants will only be addressed by their first names and will not be asked about their diagnoses or specific care providers. All data, including recordings that contain personally identifiable information (PII), will be stored on secure, password-protected computers with encryption. Once the study ends, recordings will be permanently deleted.

Dr. Dickey clarified that future changes to the questions used in specific counties must be submitted as amendments before any focus groups are conducted. The researcher agreed and explained that slight variations between counties are expected, and all updated questions will be submitted in advance.

Ms. Kurtural, referencing a similar CYBHI project she had reviewed, recommended two changes for consistency: (1) the consent form should clearly state that parents are authorizing the use of their child's first name, and (2) the team should explain in the protocol how they will handle and suppress "small cells," or data that could risk identifying individuals due to small sample sizes. The researcher confirmed that the consent form had been updated to mention the use of first names but agreed to clarify that the parent is explicitly consenting to this. For small cells, the team plans to report only aggregate data and will avoid publishing any details that could identify individuals. The researcher also agreed to make the suppression method more clearly stated in the protocol.

Dr. Schaeuble raised concerns about asking sensitive questions, specifically those related to gender identity and sexual orientation. He shared that nowadays; demographic questions that once seemed harmless could pose risks if future government actions target certain groups. He asked whether these questions were truly central to the study. The researcher responded that LGBTQ + (Lesbian, Gay, Bisexual, Transgender, and Queer) youth are considered a high-needs population under CYBHI, so these questions are directly tied to the study's goals. However, the team is willing to make these questions optional and will also include contact information for participants who want help understanding the terms.

Ms. Lund asked if the research team believed that all participants, especially caregivers, would understand the identity labels. The researcher replied that youth were more likely to understand them, and that they would consider narrowing the list if needed. They explained that the intention was to be inclusive and allow participants to feel represented.

It was confirmed that caregivers would no longer be asked to complete the screener on behalf of the youth. The screener will be completed directly by the youth themselves.

Motion: It was moved by Dr. Dickey and seconded by Dr. Schaeuble to grant the project a deferred approval under the common rule for one year, classifying it as minimal risk, pending the following specified minor revisions, which require expedited review and approval by a CPHS subcommittee of Dr. Dickey.

1. Making the screening questions about gender identity optional

2. Providing resources for respondents to have questions clarified regarding gender identity categories

3. Inserting language on how the research team will be dealing with small cells

4. Inserting language in consent form to clearly request parents to authorize the use of their child's first name

5. Any subsequent changes in research questions for specific programs will be submitted as amendments for CPHS approval

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

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

4. Project # 2024-076 (Kurtural)

Title: Evaluation of the Children and Youth Behavioral Health Initiative – Study of Certified Wellness Coaches (CWC)
PI: Dan Friend, Ph.D
Board Decision: Approved Pending Conditions - Designee Review

Discussion:

This study (study of Certified Wellness Coaches) as part of the California Children and Youth Behavioral Health Initiative (CYBHI), funded by the California Health and Human Services (CalHHS). This study evaluates the new Certified Wellness Coaches (CWC) profession by examining workforce diversity, training, impact, and sustainability in up to eight California counties.

Ms. Kurtural stated that the project involves a state agency initiative that provided funding for certified wellness coaches to support youth up to age 25 across California. Although the researchers had initially considered the project a quality assurance activity that might be exempt from full review, Ms. Kurtural clarified that the inclusion of youth interviews, recruitment incentives, and the use of data from the Department of Health Care Access and Information (HCAI) meant it needed full board review.

Researchers explained that this study is a descriptive implementation study focused on understanding how wellness coaches are being integrated into behavioral health teams. The goal is to document what is working well and what could be improved, especially so that other organizations can learn from this implementation. Six to eight organizations that received employer support grants will be included in the study. Each organization will be asked to participate in four interviews including one the person who applied for the grant, and one with the supervisor of the coach, one with the wellness coach, and one with a youth (aged 14-17) who worked with a coach. Youth interviews will last about 30 minutes, adult interviews will be 60 minutes. Youth will receive a $5 gift card for participating. The study includes two main data sources: (1) de-identified, aggregate data from HCAI about the scholarships, certifications, and grants related to the wellness coach role, and (2) qualitative data from the interviews. The research team provided a detailed list of variables they will collect from HCAI and submitted a letter of support from HCAI. They confirmed that the HCAI data is de-identified and used only in aggregate, which means no individual participant can be identified from the data. The team revised the consent forms after receiving the reviewer feedback, especially to improve readability. They succeeded in lowering the youth recruitment flyer to a 5th grade reading level and adjusted the adult and parent consent forms to about a 6th grade reading level. They also added language to ensure that parents are explicitly consenting to the use of their child's first name in interviews. Researchers emphasized that participants will not be identified in any reports. All quantitative data will be reported in aggregate, and any small cells under 10 will be suppressed to protect privacy. While first names might be mentioned during recorded interviews, they will not be included in reports. Qualitative data will be presented thematically, and not as personal stories or case studies tied to individuals. The team also clarified that interviews with youth will focus on their experience with the coach, not on why they needed help. If any youth choose to disclose personal issues, that is their choice, but it is not the purpose of the questions. Youth are allowed to skip any questions or stop the interview at any time. If distress occurs, researchers will provide mental health support resources such as 988 Suicide and Crisis Lifeline and Substance Abuse and Mental Health Services Administration (SAMHSA). All interview and contact data will be stored on encrypted, password-protected servers, and all materials will be destroyed at the conclusion of the study. The researchers emphasized that data security and participant confidentiality are top priorities.

Ms. Kurtural reminded the research team to be careful about confidentiality, since interviewees might say unexpected things. She said that even if only first names are used and not published, researchers still need to be cautious about including any details that could reveal someone's identity. She advised the team to be aware of this risk and write their reports carefully.
There were not additional comments from the committee or the public.

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

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

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

5. Project # 2024-041 (Dickey)
   Title: Health Care Payments Data (HPD) System Operations
   PI: Dionne Evans-Dean, MHA
   Board Decision: Approved

Discussion:

This project, titled "Health Care Payments Data (HPD) System Operations" had been tabled in April meeting for further review. Dr. Dickey mentioned that the committee had received one key question from Ms. Lund regarding the waiver of informed consent. Ms. Lund asked whether the waiver applies only to the creation of the database or also to any future research using the data. Mr. James Yi, and Mr. Jared Goldman clarified that the current waiver of informed consent is only for building the database and every new research project would need its own separate waiver of consent if required.

It was clarified that future research that uses Personally Identifiable Information (PII) from the HPD would need to go through CPHS for approval under the Information Practices Act (IPA). If the research is conducted by CalHHS agency, it would also require CPHS review under the Common Rule.

Mr. Yi explained that for research involving limited data sets inside the HPD's secure data enclave, CPHS review is not required by statute. However, if research involves identifiable data or is conducted outside the enclave, CPHS must review under the IPA. Whether the Common Rule applies depends on the research institution and its federal funding situation and it is their responsibility to ensure compliance, not HCAI's.

Ms. Lund expressed concern that not all researchers understand these responsibilities. She asked if anyone on HCAI's side verifies that researchers have proper IRB approval when required. Mr. Yi responded that HCAI's regulations do require detailed vetting, and researchers must meet 20+ specific requirements to access the data. A data Release Committee (DRC) is also involved in checking data protection procedures and verifying that proposed uses match HPD guidelines.

Ms. Kurtural asked if HCAI had checked that their limited data use policies aligned with federal HIPAA laws. Mr. Yi responded that although HCAI is not a covered entity under HIPAA, the agency did consider HIPAA regulations when drafting their procedures. Data use agreements are required for everyone with access, and he emphasized that these agreements are even more stringent than typical HIPAA standards.

Dr. Schaeuble raised concerns about the lack of a clear summary of what rules apply to each type of data release. He wanted to know whether the laws HCAI follows are the minimum standards (a floor) or the maximum (a ceiling). Mr. Yi clarified that the statutes act as a floor, meaning HCAI can choose to apply stricter rules if appropriate. Their internal Data Release Committee and Advisory Committee were involved in setting additional regulations.

Dr. Krawczyk described the four types of data sets that can be requested from HCAI. First is the Standard Limited Dataset, which includes commercial and Medi-Cal data but excludes all direct identifiers for patients, providers, and health plans. Next is the Standard Limited Plus, which adds identifiers for providers and health plans but is only available in the secure data enclave but not through direct transmission. The third type is the Custom Limited Dataset, which is created based on the researcher's request Even though it excludes direct identifiers, each element requested must be justified based on necessity and sensitivity. Finally, there is the Research Identifiable Dataset, which can include identifiers like first and last name, address, Social Security Number (SSN), and data of birth. These are highly restricted and only approved for direct transmission if it is clearly justified why the secure enclave cannot support the researcher's needs.

HCAI team clarified that no data, not even de-identified outputs, can leave the secure enclave without explicit approval. This helps maintain privacy, confidentiality, and control over sensitive information. Research identifiable data also requires review by the Data Release Committee (DRC), especially if it will be transmitted directly.

Ms. Kurtural expressed concerns about whether all identifiers under HIPAA are included in the Research Identifiable Dataset list. For example, HIPAA considers emails, phone numbers, and account numbers to be identifiers. She emphasized the importance of staying compliant with federal law, as CPHS is responsible for approving HIPAA waivers. She noted that the list currently shown only contains a few identifiers and may not reflect the full scope of what is considered identifiable under HIPAA.

Dr. Krawczyk stated that many of the identifiers mentioned, like email addresses or medical record numbers, are either not collected or not available for request. The list shown represents only those identifiers eligible for request. HCAI team mentioned that more detailed documentation is available online and that they could share the complete list used for review. Dr. Schaeuble asked if the team could prepare a side-by-side comparison showing all four types of data sets along with the specific identifiers available in each and the corresponding researcher requirements. This would help the committee get a clearer picture. HCAI team agreed and proposed a 10-minute break so that they could compile the requested information for the committee to review later in the meeting.

The meeting resumed with HCAI presenting a detailed overview of the data variables in the HPD system, including how those variables are categorized and reviewed. They started by showing a "variable justification grid" which researchers must complete to justify access to specific data points in custom limited data or research identifiable datasets. They explained that the Standard Limited and Standard Limited Plus datasets contain no direct identifiers and were

built using HIPAA's definition of a limited data set. Custom Limited and Research Identifiable datasets may include direct identifiers, but requests are thoroughly vetted, and justification is required for each field. Ms. Kurtural asked for clarification about certain data fields, like policy numbers, claim control numbers, and how they are treated. It was confirmed that only encrypted versions of sensitive fields are available in custom limited data, and full identifiers are only available through research identifiable datasets, which require CPHS review. The HCAI team also demonstrated what is inside the Standard Limited dataset, including examples like:
No names, no full addresses, no date of births (DOBs) and just age and ZIP code which includes 5 digits only.

Claims data including procedures, admission/discharge dates, and payment information.
An internal member ID is used to track a person's claims across years and sources without identifying them.

HCAI displayed a slide for side-by-side comparison of the four datasets. They mentioned that Standard Limited/Plus requests may undergo optional review by the Data Release Committee (DRC) and Department of Health Care Services (DHCS) if Medi-Cal data is included. They also mentioned that Research Identifiable Data always requires CPHS and DRC approval and without DRC approval, the request cannot proceed. Researchers are encouraged to begin their CPHS application early, to ensure user information matches across applications. Including a DRC resolution letter in the CPHS application can help CPHS reviewers confirm what variables were approved for release, aligning both entities' oversight.

Dr. Johnson asked whether vital records were included in the HPD database. HCAI confirmed they are not currently included, but researchers could request to link to vital records through a separate process that requires the Vital Statistics Advisory Committee (VSAC) approval.
Dr. Schaeuble also asked about data linkage. HCAI explained that when researchers want to link HPD data with outside data sources, the requested variables, linkage methods, and end products are all reviewed for privacy risk. Also, HCAI checks if researchers have permission to bring outside datasets into the enclave and ensures appropriate use agreements are in place. If the linkage request involves research identifiable data, it must go through CPHS. HCAI clarified that direct transmission of any data must go through the Data Release Committee (DRC).
No public comment was provided.

Motion: It was moved by Dr. Dickey and seconded by Ms. Kurtural to approve establishment of the Health Care Payments Database.

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

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

F. Full Board Continuing Review

None.

G. Amendments – Full Committee Review Required

1. Project # 2023-171 (Lund)
   Title: Community Health Workers, Healthy Homes, and Healthy Families
   PI: Alma Torres-Nguyen, MPH
   Board Decision: Approved

Discussion:

Ms. Lund informed the committee about the amendment that expands the population eligible for recruitment and allows researchers to recontact individuals previously enrolled. She emphasized that these changes were significant enough from a human subject's perspective to require full board review.

Ms. Ramirez from the research team explained the changes, noting that the study population now includes patients enrolled in Kawai Health through the Teluria County managed care plan. This change was necessary because the original target group did not provide enough eligible participants for weatherization and energy services. Kawai Health created a master list of 157 patients who met initial eligibility. However, many of them were ineligible for weatherization due to their housing situation and living in apartments, transitional homes, or other non-qualifying arrangements. Only 21 of the 157 patients (13.4%) were potentially eligible, with 8 completing the intake survey. These 8 participants will pause participation until the amendment is approved, which includes a new intake survey with expanded questions.

The consent forms, HIPAA forms, and survey questions were updated to reflect the new population and include research on the impact of weatherization services on health. The data collection period was also extended from 6 to 12 months. Ms. Ramirez clarified that they will not be reconsenting 8 households who are awaiting weatherization, as their eligibility and the services offered have not changed. Based on committee guidance, reconsent is not required if there are no major changes to services and participants were already consented.

Ms. Lund concluded by opening the floor for board question. No questions were raised by committee. No public comments were received.

Motion: Ms. Lund moves and Dr. Johnson seconds to approve; minimal risk and all other timelines remain the same for the project.

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

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

H. Second Review Calendar

None.

I. New Projects – Expedited Review Requested

Some projects listed may have been approved by expedited review prior to this meeting and were not reviewed by the full committee.
Total Project Count (14)

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 (38)

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 (98)

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 (20)

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

None.

M. Exemption/Not Research Approvals

Total Project Count (5)

N. Final Reports

Total Project Count (9)

O. Public Comments

None.

P. Next Meeting

The next CPHS meeting is scheduled to be held on Friday, August 1, 2025.

Q. Adjournment

This meeting was adjourned at 11:58 AM on June 6, 2025.