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

Darci Delgado, PsyD. (Interim Chair)
Larry Dickey, MD, MPH, Vice Chair
Juan Ruiz, MD, DrPH, MPH
Alicia Bazzano, MD, PhD
Maria Dinis, PhD, MSW
Catherine Hess, PhD
Laura Lund, MA
Philip Palacio, EdD, MS
John Schaeuble, PhD, MS
Maria Ventura, PhD
Jonni Johnson, PhD

Remote Attendees

Larry Dickey, MD, MPH, Vice Chair
Juan Ruiz, MD, DrPH, MPH
Alicia Bazzano, MD, PhD
Maria Dinis, PhD, MSW
Philip Palacio, EdD, MS

Friday, April 5, 2024
8:30 a.m.

Zoom:
CPHS April 5, 2024, Full Committee Meeting

Meeting ID:160 413 3950
Passcode: 482211

Location:
1215 O Street,
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Meeting ID:160 413 3950

MINUTES

CDII
Agnieszka Rykaczewska, Deputy Director

CPHS Administrator
Agnieszka Rykaczewska, PhD

Committee Members Present in Person:
Darci Delgado, PsyD.
Catherine Hess, PhD
Laura Lund, MA
John Schaeuble, PhD, MS
Maria Ventura, PhD
Jonni Johnson, PhD

Committee Members Present Remotely:
Maria Dinis, PhD, MSW
Philip Palacio, EdD, MS
Larry Dickey, MD, MPH
Juan Ruiz, MD, DrPh, MPH
Alicia Bazzano, MD, PhD

CPHS Staff Present:
Agnieszka Rykaczewska
Lucila Martinez
Sussan Atifeh
Karima Muhammad
Nicholas Zadrozna

California Health and Human Services Present Remotely:
Jared Goldman

Also, Present (All via ZoomGov) Principal Investigators and Associate Investigators:
Bridgett Lery, Urban Institute
Katina Brewsaugh, Urban Institute
John Pugliese, CDPH
Jessica Gollaher, CSUS
Levi Evans, CDPH
Robin Haynes, Harvard University
Elisabeth Haas, UCSD
Amanda Lechner, Mathematica
Gina Sgro, Mathematica
Holly Matulewicz, Mathematica
Sharon Manne, Rutters Cancer Institute of New Jersey
Ouahiba Laribi, OEHHA

A. Welcome and Chair Updates

a. Welcome

Dr. Delgado, CPHS Chair, calls the meeting to order welcoming both in-person and remote attendees. Sussan Atifeh, CPHS staff, took roll call and established quorum. Since the new edition of Bagley-Keene Act, committee members attending remotely are reminded to have their cameras on and be visible during the committee meeting.

b. Update from March 1st, 2024, CPHS Special Full Board Meeting

The full analysis of Common Rule vs. Information Practices Act (IPA) is still in progress. We anticipate it to be an agenda item at the next CPHS meeting, June 7, 2024. A detailed analysis explanation will be provided, with time allocated for questions. The participation and insights of members are appreciated.

Dr. Delgado, CPHS Chair, emphasizes the importance of closing loops on CPHS action items. Given that CPHS meets only once every two months, ensuring action item closure can be challenging. CPHS Administration is actively working to streamline this process.

Discussion will be held on regulations pertaining to charging entities outside of CalHHS that utilize CPHS as an Institutional Review Board (IRB). An agenda item during the June 7, 2024, committee meeting will have a presentation that will cover costs, fees, and the overall process to start charging fees in future years. This will be an incoming revenue in the future for CPHS.

B. Administrator Updates

a. Collaborative Institutional Training Initiatives (CITI)

Agnieszka Rykaczewska presented updates on collaborative institutional training initiatives (CITI). Procurement challenges are being addressed and actively being resolved. Item payments are being processed and will soon be available for committee members and admin staff for access. Once CPHS obtains access to the CITI dashboard, CPHS staff will draft instructions and provide them to committee members on how to access the trainings. Following are the six trainings that will be available to both committee members and CPHS Staff:

1. Human Subjects Research
2. Information Privacy and Security
3. IRB Protocol Review
4. QA/QI Human Subjects Research
5. IRB Administration (Comprehensive)
6. Becoming an Effective Leader

b. The California Health and Human Services Agency (CHHS) Emails for CPHS Committee Members

CalHHS based emails are provided to Committee Members to ensure the privacy of their correspondence related to CPHS business. Instructions on setting up these emails were sent earlier this month by CPHS staff, Nicholas Zadrozna. Support is available throughout the setup process, and automatic mail forwarding can be arranged to minimize the need to access multiple mail inboxes. Committee Members are encouraged to work with Nicholas Zadrozna for set up assistance.

c. One-on-One Meetings with CPHS Committee Members

Agnieszka will continue to contact the remaining Committee Members individually to schedule one-on-one phone calls for several purposes including but not limited to:

1. Providing an opportunity to get acquainted and share more about herself
2. Addressing questions, concerns, and suggestions.
3. Facilitating learning and knowledge sharing

Agnieszka Rykaczewska expresses gratitude to the Committee Members who have already met with her. Her aim is to offer support in any way possible for CPHS. Additionally, Committee Members are encouraged to reach out with questions and concerns at any time.

d. Notice of Federal Proposed Rule Making: Draft Guidance on Key Information and Facilitating Understanding in Informed Consent

CDII legislative staff notified CPHS of a public comment opportunity from a Federal Proposed Rulemaking. Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) have released draft guidelines for key information to facilitate understanding in informed consent. The guidance includes seven key pieces of information regarding elements of informed consent, along with formatting, organizing, and presentation guidance to enhance understanding:

1. Voluntary Participation and Right to Discontinue Participation
2. Purpose of the Research, Expected Duration, and Procedures to Be Followed
3. Reasonably Foreseeable Risks and Discomforts
4. Reasonably Expected Benefits
5. Appropriate Alternative Procedures
6. Compensation and Medical Treatments for Research-Related Injuries
7. Costs Related to Subject Participation

The guidance also introduces the use of bubbles in the Key Information Section to enhance comprehension and provides formatting examples in the Appendix. OHRP and the FDA seek public comment on this guidance, emphasizing that it is intended to aid in implementing existing rules on informed consent.

Committee Members have two options for providing public comment:

1. Submitting individual comments to the Federal Government by April 30, 2024.
2. Submitting a formal comment on behalf of CPHS.

Dr. Schaeuble proposed a formal comment response. The example was displayed for meeting attendees:

"The California Committee for the Protection of Human Subjects strongly endorses efforts to make consent information more understandable and supports [in principle] the proposed federal guidance."

Dr. Delgado asked for feedback from other Committee Members who reviewed the guidance.

Dr. Dickey, CPHS Vice Chair, expressed agreement, stating this non-binding guidance was well written and supporting Dr. Schaeuble proposed statement.

Dr. Delgado agreed the guidance was well done. If CPHS does accept this as guidance, it should be posted on our website. The guidance is helpful to visual learners and requested a motion.

Dr. Dinis expressed concern about CPHS adopting the non-binding guidance. She questioned how CPHS would resolve conflicts with this guidance if other researchers held different viewpoints from what the guidance suggests.

Dr. Dickey suggested posting the guidance as a resource, emphasizing its usefulness in enhancing participant comprehension. He also recommended providing links to other OHRP guidance on the website.

Dr. Delgado requested clarification on the version of Dr. Schaeuble's suggested formal statement to be used, and Dr. Dickey confirmed the following:

"The California Committee for the Protection of Human Subjects strongly endorses efforts to make consent information more understandable and supports the proposed federal guidance."

Dr. Dickey inquired whether CPHS should mandate the guidance or merely make it available as a resource.

Dr. Delgado advocated for making the guidance accessible as a resource. Dr. Delgado also noted that researchers often struggle with gauging participant reading levels and comprehension, emphasizing the guidance's utility in enhancing participant understanding.

Dr. Dickey referenced the Resources and Downloads section on the CPHS webpage, which contains examples and samples of consent and assent forms in a bulleted list format. He highlighted the use of bubbles in the federal guidance as a mean to visually represent information, suggesting various formatting options based on the length of consent forms. He sought the Committee's support for the proposed guidance.

Dr. Dickey suggested providing links to other OHRP guidance on the website, as it is an underutilized resource.

Dr. Delgado sought clarification on which version of Dr. Schaeuble’s suggested formal statement would be used. Dr. Dickey confirmed the following:

The California Committee for the Protection of Human Subjects strongly endorses efforts to make consent information more understandable and supports the proposed federal guidance.

Motion: Dr. Dickey moved, and Dr. Hess seconded the motion to approve Dr. Schaeuble's suggested formal comment to OHRP in support of Federal *Draft Guidance - Key Information and Facilitating Understanding in Informed Consent.*

Approve: Dr. Ruiz, Dr. Bazzano, Dr. Dinis, Ms. Lund, Dr. Schaeuble, Dr. Ventura, Dr. Johnson
Oppose: None
Abstain: None
Absent: Dr. Palacio (he didn't respond when his name was called)

Dr. Delgado expressed gratitude to Dr. Schaeuble for leading the drafting of the responded language. CPHS Members were reminded that as individuals they are not precluded from submitting their own public comment. Comments are due on April 30, 2024.

C. Introduction to the Department of Health Care Access and Information (HCAI) Health Care Payments Data (HPD)

Dr. Delgado introduced Michael Valle, Chief Information Officer, and Deputy Director, HCAI. This concept of databases will need to be addressed by CPHS in the next upcoming months. Protocols and access to the data will increase and is ongoing. Michael Valle's presentation will help Committee Members become familiar with the Health Care Payments Data (HPD). Michael Valle looks forward to a continued partnership with CPHS. The HCAI PowerPoint presentation is shared on the screen for all attendees.

Michael Valle opened the presentation with the following statement, on slides one and two:

> *As you likely know, but I'm obligated to say our department has a long history as a health data organization supporting informed decisions in the state, and I like to remind people that we were one name for almost 50 years, and we've now changed that name from the Office of Statewide Health Planning and Development in July of 2021. We like to say we graduated from an office to a department, the Department of Health care Access and Information (HCAI). It's an additive change. We're expanding our portfolio of programs, doubling down on our mission to expand equal access to healthcare for all Californians.*

Michael Valle continued to slide three with the following statement:

> *You'll just see here a description of the various health data and transparency programs.*
> *HCAI oversees, again by way of background and introduction, you may know that HCAI administers California's hospital discharge database and has since the 1980s, which collates over 15 million records annually of inpatient discharges and emergency department encounters with the form outcome studies for cardiovascular and procedures. That part bypass surgery, among the other data programs you see on the screen. In 2023, we published over 50 discrete, de-identified data sets as well as 60 online visualizations and interactive reports for public use.*
> *Last year, we also fulfilled over 200 requests for nonpublic identifiable data, many of which passed through this committee.*
> *And so, we're just so proud of this significant contribution HCAI data has made to the body of knowledge for health policy and practice and for the committee's role in helping us do that.*

Michael Valle continued to slide four with the following statement:

I'll now move to an overview of the healthcare payment database or HPD, California's All Payer Claims Database, also known as an APCD. It is our newest data offering – a retrospective research database, the only all payer state run claims database in California, we call it Health Care Payments (HPD) to reflect the prevalence of managed care and value-based payment in the state, and our goal to include non-claims-based payments into the database in the future.
20 of the states have similar data systems. This has been a long-time coming state policymaker, others have been working since 2007 to establish a state APCD in California.
We're standing on the shoulders of giants with this learning from others and the many claims' data warehousing efforts that have come before us.
In 2018 HCAI received the initial startup funding to begin studying and planning for how to build a database. In 2020 the additional enabling authority to establish the database was granted.
Since then, we've been heads down building our team, working with data suppliers and other stakeholders and engineering technology infrastructure to support the database. And I'm now very proud to say that we have 4 plus years and growing of historical data loaded into the system. That's 5 billion healthcare claims, 17 billion total records, the single largest data aggregation of our department's history. And we're now successfully collecting and processing over 100 million new healthcare claims encounters each month. So, the database continues to grow.

This is data from all healthcare payers, the claims, the encounters for services provided under manage care arrangement, but with some limitations, as I think was mentioned, the uninsured, self-pay, self-insured EA, for example, are not included.

This is administrative data. There's no clinical data included in the database and some health plans are also exempted from reporting. The database includes over 80% of the CA population for calendar year 2021, we have over 33 million unique covered lives represented. We are closely monitoring data quality and completeness in the database and expecting data quality to improve and the usefulness of the data to improve as the database matures. I'm really thankful to California's health plans and insurers that have been fantastic partners in this effort, supplying high quality data according to HCAI specifications and without their partnerships, the progress made on this work today would not be possible, and also I'd like to thank partners in the California Health and Human Services Agency, California Department of Health Care Services (DHCS) , who supplies all the Medi-Cal data for Fee-for-Service and Medi-Cal Managed Care plans.

Dr. Delgado asked when CPHS will begin moving towards looking at similar projects. Examples: Medi-Cal information is pouring into the database. Questions about approval for use of the DHCS data versus HCAI. This is a good starting point for upcoming discussions.

Michael Valle agrees and continues with the fifth slide:

> *HCAI has adopted a national standard for claims and encounter data, which is ratified by stakeholders Advisory Committee in 2020 and includes common information for billing such as the patient's diagnosis, the procedure performed, the amount paid for a claim, provide information, pharmacy information and more.*
> *We expect it can be used to support many big data longitudinal system analysis on healthcare costs, utilization, quality access, and equity.*
> *And we're just very excited about what the research community and others will be able to achieve by using this data.*

Dr. Delgado asked about the database not holding 'clinical information'.

Michael Valle responded that clinical information would include lab information, clinical notes. The example in slide five shows information from an administrative database referencing billing information included in health plan systems for billing purposes. There are key gaps in the information. Information not required to pay a health care claim may not be represented in the databases. It can be used to generate key quality measures.

Dr. Delgado expressed CPHS would like push back on the statement that the claim does not include clinical information as claims couple patient names with diagnosis.

Michael Valle acknowledged Dr. Delgado's input and continued with the presentation:

> *We've adopted a national standard for this database that is governed by The National Association of Health Data Organizations (NAHDO). Which oversees all payers claim database Common data layout.*
> *HCAI is an active member of NAHDO, and HCAI staff sit on the NAHDO Board of Directors.*
> *HCAI is very proud to lead the addition at the national level of more granular race and ethnicity categories, and for the first time the addition of sexual orientation, gender identity data into the all-payer claims database common data layout.*
> *The Office of Management and Budget (OMB)'s rule recently is showing similar guidance, and the NAHDO and the All-Payer Claims Databases (APCD) Council ratified these changes in September of 2022 for all state APCD's to adopt. The California health plans began submitting data to HCAI HPDs with the more granular categories in January 2024.*

Michael Valle continued with slide six:

> *The database is intended to be used by a wide variety of audiences, public and private. We want healthcare entities to use this data to help them improve and to collectively implement policies that can make the healthcare system better. You can see the goals on the screen.*
> *These are enumerated in the California Health and Safety Code that further been adopted by our stakeholder Advisory committee. However, the HPD program must provide a benefit to Californians and the use of the data must protect individual privacy. Next slide, please.*

Michael Valle continued with slide seven:

> *There are two governing bodies responsible for oversighting, the administration of the Healthcare payments database.*
> *The Advisory Committee that is a policy level committee that advises HCAI program policies. It's made of Across Sector group payers, providers, researchers, consumers, and others, it has been quarterly since 2020.*
> *HPD is also overseen by a Data Release Committee (DRC) which is also diverse, across sector groups, made of technical data, privacy experts, also representing various parts of health care system, and his role is to review requests for access to non-public data and to advise HCAI of matters of data use, data privacy, and data security.*

Ms. Lund asked if either of the Advisory Committee or the Data Release Committee participants are required by statue, or if they are volunteers.

Michael Valle noted the participants are required in statue, along with their representation, their roles, and responsibilities and continued with slide eight:

> *There are two ways the data in HPD can be used like other HCAI data resources, our analysts and researchers internally produce public reports, on topics of import to healthcare policy and practice, the de-identified data we've published on the HCI website, and we've released two public analytic reports from the HPD so far and will continue to release new ones ongoing.*
> *Additionally, we have a data release program as we do for our hospital data, we are in the process of designing such a program for the claims data.*
> *This program is expected to begin accepting requests later this year, and we are meeting regularly with the Data Release Committee to develop that process in collaboration with them.*

Michael Valle continued with slide nine:

I'd like to just give a quick overview of some of the public reports that have been published.
Each of these has hundreds of thousands of rows of data available.
The underlying deidentified information is downloadable, machine readable and Application programming interface (API) enabled.
First, HPD snapshot hcai.ca.gov/snapshot.
The purpose of this product is providing an overview of what data is available in the HPD system.
If you add it up, it's over 5 billion claims and encounters where four-year period there are four distinct views in this report.
So, for instance, you can see the number of covered lives by pay or a line of business
They're working to get more granular with the filters we provide there.
You can also view by month and line of business.
The number of services received and compare that to the number of members eligible for care in that line of business.
It also includes the top medical procedures and the top prescriptions filled by number of claims.

So, you can see our data shows there were 334 million office visit claims billed from 2018 to 2021 is the top build medical service states 2,000,000 claims of particular statin agent during the same time as a top bill prescription drug.
And we think this report really provides a foundational look into the data to get people familiar with the database and its contents and may inform subsequent requests for the detailed record level data through our nonpublic data release process.
2nd HPD measures HCAI dot.ca.gov/measures present standardized chronic condition demographic and utilization measure categories, filters for up to 23 measures per category and additional filters for up to two simultaneous grouping dimensions, including age, band, county, sex, payor, and more, with the ability to compare the statewide averages.

We include several starting prompts to demonstrate what you can do with this report.
For example, what percentage of Californians in my age group have a diabetes diagnosis?
Or is the number of surgical inpatient stays increasing or decreasing over time across the state?

We recently presented this report to a coalition of local health officers and there was a lot of interest in it, and we are very excited about this report and to continue to add new measures and provide more granular dimensions of filtering and analysis in future years.

Our next report will be released very soon.
We are workshopping the final design of a pre scription drug costs report.
Now we are very excited about our first look at cost information from HPD data.
The HCAI advisory committee made recommendations for three priority topic areas that HCAI should focus on in 2024 for new public reports.
First, social drivers of health and HealthEquity. We're planning to look at the Healthy Places Index and other place-based indices for social determinants.
Then, we want to further enhance the prescription of report.
We're preparing to publish soon with more data elements. Finally, we are looking at hospital costs as our second foray into cost reporting from the HPD and certainly unknown cost driver for total cost of care across the system.

We also plan to refresh these two reports CMS screen snapshot and measure it's with two New Years of data that's 2022 and 2023 Data will be added at the end of this year, so we're very excited about that as well.

Dr. Delgado requested clarification about what is available online and if the de-identified individual line-by-line is available to download.

Michael Valle responded as follows:

Right. It's de-identified at the data element level, so there are suppressed cells in the underlying data because they need to be suppressed in any sort of measure category grouping that might be presented in the online visualization.

Dr. Delgado asked what de-identification policies HCAI followed. Michael Valle advised they follow the CalHHS data de-identification guidelines.

Dr. Bazzano asked if there was a bioethicist in the Data Release Committee (DRC).
Dr. Delgado supported Dr. Bazzano's question by asking Michael Valle to explain to CPHS HCAI's recruitment process.

Michael Valle responded as follow:

> *We have Dr. Barbara A. Koenig, Professor Emerita of Bioethics, University of California, San Francisco is our bioethicist in residence. There's also a slide that scribes their roles and backgrounds. Again, the statute requires a cross sectoral group, so we have representatives again from the payer community, from the provider community, from the research community, and with experience in data privacy, data security, healthcare, healthcare data.*
> *So yes, we are so just proud and thankful and grateful for this this group to be helping us with this project.*

Michael Valle continued in describing the data release program:

> *Regarding the data release program that we're in the process of developing, I want to start with something that's foundational to our program and that is providing access to nonpublic data and secure online research data on play.*
> *We're in the process of testing that system now. Our statute contemplates the approach of providing virtual access to data where the data remains on HCAI servers but can be viewed and analyzed through remote desktop environment with preloaded statistical analysis tools is the best way to preserve individual privacy and maintain information security.*
> *We're committed to that as it aligns with our values, we're providing data access while balancing the risk in use of the data.*
> *There will be a high bar for that, since our statute does permit transmitting data outside the database, and the Data Release Committee must affirmatively approve any such request.*
> *Additionally, the HPD Statute contemplates two types of data sets for release, a standard limited data set with direct and some indirect identifiers removed, and a research identifiable data set which may include direct identifiers for qualified researchers and for research purposes.*
> *It's the request for the identifiable research data by academic researchers that also requires this committee's involvement to evaluate those, and we like for our staff to work together to make an effective and efficient process for our programs and members, and the researchers requesting that data.*

Dr. Delgado read Dr. Bazzano's questions from the virtual chat:

1. Who will be allowed to utilize this information under this non-public data release?
2. What are the qualifications?
3. Questions about for-profit entities, lobbying groups?

There are a lot of interested parties in these data sets when it comes to potential users.

Michael Valle responded as follows:

> *Yeah, it's fantastic and something we've been spending so much time evaluating and unpacking, our committees have been critical to that, happy to share the materials, perhaps offline, if that would be helpful.*
> *I think what we feel is the statue really suggests that this data should be widely used and utilized to meet the goals of the program and that healthcare entities have a role in controlling costs and improving the quality and improving access.*
> *For accessing the information there will be a case-by-case review on any harms that may come from the data use and if the benefit of data use outweighs those. So that's built into our process, and happy to share more on that.*
> *And again, we are really going to be relying on our committee of stakeholders and experts to help guide us through, especially those challenging edge cases which we don't know which types of ideas for use of the data will emerge.*

Ms. Lund asked, does your statute have limitations on who can receive the data? She noted that some state data cannot be released to for-profit entities. There may be additional restrictions, and it may depend on the dataset.

Michael Valle responded as follows:

> *Yes, that's a great question. The research identifiable data is only available to researchers for research purposes. The standard limited data does not have those type of restrictions, and so again we are going to be eager to see what types of uses are proposed for use of that standard limited data set.*

Dr. Maria Ventura, Committee Member, asked a question about violations in the use of the data and reporting the violation to the Data Release Committee.

Michael Valle responded as follows:

> *It's something we've talked about at length.*
> *In terms of oversighting the use of the data, we have data use agreements in place that are continually being strengthened to ensure careful monitoring within our analytic environments. I think the public committee will be a good resource to help ensure that using data is appropriate and protected since this committee is tasked with overseeing the identification procedures for any outputs that are disseminated.*

After Dr. Delgado and Dr. Bazzano noted the large amount of information to unpack which will lead to a series of discussion through the end of 2024, Michael Valle continued as follows:

> *There's so much interest in this database.*
> *We're finishing the rulemaking process, which is necessary to begin our data release program.*
> *We think that will be done in the second quarter (Q2) and then we will begin accepting requests and going through the process that will be familiar to many of you. Our staff will intake those requests, perform some initial triage, working with requesters, checking to clarify if any approval from the Department of Health Care Services (DHCS) is required, etc.*
> *So, we are working very closely with DHCS to make that an efficient part of the process. And research identifiable requests by researchers also need to come before for this body, and we'd love to work closely with you to ensure an effective process.*

Dr. Delgado read Dr. Dinis virtual comment as she asked about merging data sets with existing data sets that the researchers are holding themselves. Will there be a matching aspect?

Michael Valle responded as follows:

> *Yes, absolutely, the potential for data linkage is quite promising.*
> *We want to have a 'bring your own data' feature within our online data enclave.*
> *We have a master person index to facilitate those processes. I think when it comes to data linkage, a higher level of scrutiny may be appropriate depending on the usage type. But certainly, supporting longitudinal and systemic research through such data utilization is a priority for us.*

Dr. Dickey advised CPHS is discussing these issues with HCAI staff with Jennifer, a CalHHS attorney. In response to Ms. Lund's question, HCAI data is subject to the Information Practices Act, which is where CPHS becomes involved.

Michael Valle responded as follows:

> *Well, I'm not an attorney myself, despite my fantastic sport coat that Darci pointed out, I think that we should have our teams maybe talk more about that.*
> *I think what's unique about our program is that the statute explicitly provides a data release program for this database and explicitly defines this committee's role in that process.*
> *So, I think that may be something that the team should discuss more.*

Ms. Lund noted vital statistics have their own legislation. Instead of SB 13, CPHS is governed by the Vital Stat Legislation. Dr. Dickey agreed legal input would be valuable. Dr. Delgado read a question asked through the virtual chat about if Michael Valle interacts directly with the Office of Human Research Protections (acronym OHRP),

Michael Valle responded as follows:

> *I have not myself. I'll have to get back to you to see if the program has.*

Dr. Schaeuble asked about releasing identifiable data to researchers and if there were limitations on researcher affiliations.

Michael Valle responded as follows:

> *We do have limitations on the researcher. I will have to get back to you on what the specifics are that define that.*

Dr. Delgado noted distinctions when for-profit researchers hire another researcher to present themselves in a way that would change the risk-level review.

Michael Valle responded as follows:

That's great point you have. I will have to find that in our rulemaking, I don't have it right in front of me but I'm happy to share that with you.

Dr. Schaeuble requested clarification on if commercial entities were included along with academic institutions. Michael Valle advised he would get back to Dr. Schaeuble.

Dr. Dinis asked if HCAI data sets will be merged with data sets that researchers have in their possession. Dr. Delgado advised the data sets can merge with researchers bringing their own datasets into the HCAI enclave data. Dr. Dinis asked if the dataset would then be merged with medical information, as that exposure would create another way to identify patients that have no protection. A few years ago, a senator was identified through just three or four variables.

Dr. Delgado agreed with Dr. Dinis. She also applauded HCAI on the concept of having state-owned data space for dataset merges to occur. She mentioned, "Controlling access to data is easier than emailing huge data sets each month."

Michael Valle continued with slide 11:

> *This slide has the roster of our data release committee.*
> *Again, I'll just share that for your reference and appreciated it to them and all of you for your service to the state of California and for your time.*

Before giving the floor to public comment, Dr. Delgado asked if there were questions or comments from the Committee Members. Michael Valle's contact information is available in the virtual chat, along with the HCAI PowerPoint. This conversation will be continued at the June, with more specifics on statues, procedures, and how the Data Release Committee will interact with CPHS.

Dr. Delgado opened the floor to public comment.

Satish Kumar, CEO of Suparana Health AI, LLC provided a public comment regarding how it is hard for startup companies to get access to the data like academic institutions can access. Mr. Kumar suggested there can be a program to make it easier for start-up companies to be able to get unidentifiable data to be able to do research with. Dr. Delgado thanked Mr. Kumar for his comment and for joining the CPHS committee meeting.

Virtual public comment from Katrina; Katrina is a researcher that gathers data from multiple public entities. She expressed interest in how the committees will interact with the Data Release Committee. Katrina is interested in the hierarchical order of approval from the committees and asks what the options are if the two committees' conflict.

Dr. Delgado thanked Katrina for the feedback and assured the feedback would go to Michael Valle. She advised the committees would work towards developing clear communications and expectations.

D. Information on Assembly Bill 352

Dr. Delgado introduced Jared Goldman, the General Counsel for California Health and Human Services (CHHS).

Jared Goldman shared his screen displaying AB 352 Civil Code 56.110(a)(4). He explained that AB 352 is bill part of a broader package of changes to the law aimed at limiting disclosures of public records like electronic health records to states other than California. What is presented is just a piece of the bill, which is part of a broader portion related to California. California has some of the strongest privacy protections for providing information. There is concern about disclosures of information in the hands of providers in states that are hostile towards abortion, individuals who had abortions, or providers who participated in providing abortion services.

Jared Goldman proceeded to read Section 56.110:

> *(a) Notwithstanding subdivision (c) of Section 56.10, a provider of health care, healthcare Service plan, pharmaceutical company, contractor, or employer shall not knowingly disclose, transmit, transfer, share, or grant access to medical information in an electronic health records system or through a health information exchange that would identify an individual and that is related to an individual seeking, obtaining, providing, supporting, or aiding in the performance of an abortion that is lawful under the laws of this state to any individual or entity from another state, unless the disclosure, transmittal, transfer, sharing, or granting of access is authorized under any of the following conditions:*

Jared Goldman continues, pointing out the law provides a series of conditions with two exceptions on the limitations to disclosure:

1. Disclosures can be made pursuant to authorization.
2. Disclosures can be made pursuant to the California Confidentiality of Medical Information Act (CMIA) exception which allows disclosures for the purpose of research. This is where CPHS comes in. Jared Goldman references the highlighted section of Section 56.110, which reads:

> *In accordance with paragraph (7) of subdivision (c) of section 56.10, for the purpose of bona fide research. Institutional Review Boards shall consider the potential harm to the patient and the patient's privacy when the research uses data that contains information related to abortion or abortion related services and the research is performed out of state.*

Jared Goldman emphasizes when CPHS reviews research that involves the disclosure of abortion related information, patient-identifying abortion related information, in Electronic Health Records (EHR) or health information exchange, CPHS has a role to pause and consider the particular impacts to the women, not the providers, and the potential harm to the patient and the patient's privacy when the information is disclosed out of state.

Dr. Delgado asked the following questions and Jared Goldman's response follows in italics:

1. Is this proposed legislation or is this already an active in state law?

This is on the books, and this was effective January 1, 2024.

2. Dr. Bazzano in the virtual chat: What does research performed out of state mean? Does publication count as research performed out of state?

We don't know that from the law. It does not explain that part. We must look at it on a case-by-case basis. All law is fact based. In terms of CPHS oversight and review of research, it is essential that these issues are examined by your legal teams.

Dr. Dickey expressed about issues with how implementation happens, the Health Care Payments Database (HPD) should have an exclusive database containing information with abortions and another database that does not have abortion data. It will be difficult for CPHS to review every variable and know if data about abortion was removed or not unless the people designing the databases do that for us.

Jared Goldman responds that another portion of AB 352 includes a requirement that EHR developers are now required to develop their EHRs in California in a way that allows for the segregation of abortion data, at least with respect to electronic health records. In the future, segregation of abortion data will become easier.

Dr. Hess asked how this will impact data sets from patient discharge data, emergency department data. Many projects look at this data which includes procedure and diagnosis codes that are abortion related. How should CPHS proceed?

Jared Goldman responds, "Abortion related information that is identifiable, and being disclosed out of state, CPHS should consider the potential harms to the patient."

Ms. Lund asked if CPHS would go back to HCAI to request a dataset for out-of-state.

Dr. Delgado voiced Agnieszka mentioned AB 352 was bought to CDII attention by Michael Valle, during the development of the Healthcare Payments Database. HCAI is likely familiar with this concern. Dr. Delgado inquired about HCAI adjusting pre-released datasets from before this law was enacted.

Jared Goldman advised he does not know the answer to that question at this time and is glad for the questions. He advised this can be considered with respect to certain research projects.

Ms. Lund advised SB 13 allows CPHS to ask state agencies to remove personal identifying information that CPHS does not want to release.

Dr. Delgado suggested generating a motion to formally request that, pursuant to AB 352, HCAI remove personal identifying data.

Dr. Hess advised she works with the Enterprise Data Platform Accelerator (EDPA) data and stated researchers use the identifying information to look at repeat encounters. We don't want to say they can't have that identifying information but there needs to be a way for HCAI to remove case where there is a diagnosis or International Classification of Diseases (ICD)-9 code related to abortion services. Do we ask HCAI to remove those cases from the data set or not release identifiable information to out-of-state entities?
Dr. Delgado notes there will be an operational piece to this.
Dr. Dinis notes there are some services a patient receives for a miscarriage that are marked as abortion services. Some states may consider miscarriage as an abortion, while others consider it a necessary medical procedure. How can we separate this information, so we know what is or is not supposed to be sent.
Dr. Delgado notes Dr. Bazzano expressed similar thoughts in the virtual chat, that it is not obvious how we remove this data. Dr. Delgado suggests a sub-committee or working group to put out formal recommendations to our departments that hold data related to abortion services.
Dr. Dickey believes this cannot be done on a project-by-project basis but work with those who release the data to have a set of data that does not have abortion service data. The data set that does have abortion related services can be used in California. We might have to get rid of it in California.
Jared Goldman advised this law does not preclude disclosures of abortion-blended information outside of California, it just requires that you consider the potential harm to the patient. There may be a range of other solutions other than stopping the disclosure of the information. One way is to include additional conditions.
Dr. Dinis asked how CPHS committee members can truly define what the potential of harm is, and at the same time consider the laws of each red state. It is a big ask of CPHS to assume to know intricate details of how abortion services are being handled in other states across the country. CPHS would need to be familiar with every guideline and regulation of these states.
Ms. Lund responded that when we consider the main harm in the release of the research data to bona fide researchers out-of-state is that state law enforcement institutions will subpoena the data, which is where the real harm comes from. Instead of trying to suppress the abortion related data prior to release, CPHS could request a federal National Institutes of Health (NIH) Certificate of Confidentiality for any out-of-state studies requesting access to this information. This is believed to make the data exempt from subpoena generated by state law enforcement.
Dr. Delgado agrees with that option.
Dr. Dickey agrees CPHS investigate NIH Certificates of Confidentiality. Law enforcement is one of the exceptions under the confidentiality certificate though. Ms. Lund advised that may only be true when there is immediate harm or danger. CPHS will continue to research.
Dr. Dinis likes the idea. If the abortion related data is being viewed as a crime, it could work.
Dr. Delgado asked if there needs to be a motion for a workgroup or a subgroup.
Ms. Lund responded that a subcommittee of three or more requires a public meeting.

Dr. Delgado presents CPHS is looking for a subcommittee of two. Dr. Bazzano and Dr. Hess are officially assigned to a subcommittee of two which does not trigger Bagley-Keene. The subcommittee will pursue exploring implementation of patient recommendations for AB352. For the record, all legislative efforts are appreciated to protect the people of California who seek out abortion services.

Dr. Schaeuble advised AB 352, there is a reference to CalHHS Data Exchange Framework which was slated to be active at the end of January 2024. This relates to what Michael Valle was talking about. Agnieszka advised the Data Exchange framework is under Center for Data Insights and Innovation (CDII) and she will reach out to her colleagues to get an answer for CPHS in writing.

Dr. Delgado summarized the Data Exchange Network is a project to exchange electronic health records between entities. Agency is working towards a policy initiative to aide communication between healthcare systems. This is different from what Michael Valle was talking about.

Dr. Dickey advised the two might be related if there was an exchange of information out-of-state. Dr. Dickey then asked if there was a motion and if so, the subcommittee should work with legal to develop. Dr. Delgado noted Dr. Bazzano and Dr. Hess will consult with legal on this topic as well. Dr. Delgado thanked Jared Goldman for joining the CPHS meeting.

E. Proposed Revisions to the CPHS Policy and Procedures Related to Unanticipated Problems

Dr. Delgado notes this topic was discussed across multiple meetings. There were some documents emailed that contained information about this item.

Dr. Dickey advised a proposed revision was originally sent out. There was one section changed about the chair or vice chair could decide if a problem would need to come before the entire committee. Dr. Dickey asserted the language, then Dr. Schaeuble advised that additional corrections were needed. A different version of the policy was emailed on April 4. The document is shared on screen and there is Office for Human Research Protections (OHRP) guidance at the bottom of the document advising IRBs are free to develop their own procedures for reviewing adverse and unanticipated events. The full committee does not have to review every adverse or unanticipated event. The policy is changed as follows:

> *Unanticipated problems, but not adverse events, the Chair or Vice Chair and the primary reviewer may determine if review by the full committee is not necessary and can approve proposed revisions. However, rejection of proposed revisions can only be made by the full CPHS.*

Dr. Dickey advised this can save more time in the meetings if more of this is done in the background and we don't require researchers to come to us in person for every unanticipated event. Dr. Dickey provided an example of an unanticipated event, such as a protocol deviation that does not cause adversity.
Dr. Delgado thanked Dr. Dickey for the summary and the OHRP reference. Dr. Delgado asked for a motion from Dr. Dickey.

Motion: Dr. Dickey moved, and Ms. Lund seconded the motion to adopt the changes in the wording for the adverse and unanticipated events in the policies and procedures.

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

Total=10 In Favor-10, Opposed-0, Abstained-0

F. Update on Vital Statistics Advisory Committee (VSAC) applications

Dr. Delgado provided background that within the Department of Public Health, there is a Vital Statistics Advisory Committee that requires researchers renew their approvals every five years. CPHS conducted outreach to CDPH and VSAC to determine the process ensuring when researchers request continuing reviews from CPHS, they fulfilled the CDPH VSAC requirement to get their renewals every five years. For more than five months, CPHS has worked to align procedures to address this issue. In the last two weeks, CDPH VSAC advised due to resources they are not able to address CPHS' request. It is then difficult for CPHS to dig through protocols and align dates. CDPH does not have the bandwidth to address either. CPHS has discussed the potential solution of adding a self-attestation manager to the IRB Manager. They will track the CDPH VSAC five-year renewals for researchers, as part of their continuing review. Dr. Delgado asked if there were other ideas or comments.

Ms. Lund recalled a major adverse event occurred 18-months ago, and it was discovered researchers were releasing vital records birth data to other researchers and had done so for years. VSAC was aware and CPHS took a closer look at their procedures for vital records data and how long some of the studies last. Some researchers received data and shared it before the rules were updated. CPHS decided for research projects using vital records data to ask that every five years when they come back to CPHS to renew their project, CPHS wants to see they've gone to VSAC to ensure they continue to be aware of the rules about data and if there were changes to the study, they had informed VSAC. This will give them a chance to align their CDPH VSAC application with CPHS's. CPHS found when they come to us for review or amendments, they have not told VSAC. This change increased the burden on CPHS admin staff. We are exploring ways CPHS can continue to scrutinize the applications and ensure researchers are doing the right thing, and not overwhelming our own staff. CPHS reached out to CDPH for help with the five-year scrutiny, triggering reapplication, and proving information on upcoming protocols for the five-year deadlines. This will help CPHS staff be proactive. CDPH is unable to assist at this time. Ms. Lund advised she is not sure what can be done. Ms. Lund would like to be sensitive to what the CPHS admin staff might need. Ms. Lund expressed the self-attestation idea would help if it was broken down, so the researchers must sign off on each of the elements. Approval from VSAC is needed before CPHS moves forward with continuing reviews. If CPHS knows the researchers have applied, pending the receipt of the Letter of Support and Approval, then get their final approval letter from VSAC, making it a quicker process for CPHS admin and the researchers. CPHS does not need the final letter in hand to review and approve, if CPHS knows the researchers are going through the approval process.

Agnieszka advised the goal of Common App is to create centralized place to see if researchers have applied with CDPH and VSAC. The proposed app would guide them to apply so researchers know what is due and what is required. Researchers could not proceed without taking the required steps. The goal is not to replace CDPH's system, but to get the two systems to communicate and guide the researchers through departmental addendums. Based on the data request, the system would be triggered to send the researcher back through the VSAC application with guidance on next steps. Upon completion, the system would notify CPHS of completion of the application process.

Sussan expressed that a significant portion of the workload involves comparing the revised VSAC application with the CPHS application to ensure both are consistent. This process is quite time-consuming. Importantly each time CPHS Committee Members require revisions, the VSAC application must be revised, and compared again to maintain consistency. CPHS admin is not fully familiar with the multiple applications used by CDPH, including their specific uses and limitations. Sussan asked if both applications need to match perfectly before being assigned to the Committee Members, and she questioned who has the authority to make that decision?

Ms. Lund responds that she always looks through both applications very carefully as she has had the experience of researchers not having the two applications matches. Ms. Lund requests that a revised application be a part of the package so a Committee Member can complete the comparison, even if the CPHS admin staff have already done it. Sussan asked Ms. Lund about any suggestions for other committee members regarding the comparison of the two applications.

Dr. Ventura advised she was looking at a proposal that had a VSAC application attached. She also conducted a thorough review to make sure things matched up on the two applications. It helps to have the VSAC application attached to the CPHS application once it comes through. The application review falls on the Committee Members.

In summary, Dr. Delgado confirms its duplicative for staff to do a side-by-side review of the VSAC and CPHS applications and there is a pivot from staff to make sure the document is there deferring the side-by-side review to the primary reviewer.

Dr. Schaeuble expressed that when looking at the VSAC application and the CPHS application, it's easy to see that the data itself is the same. The VSAC application does not show the full text submitted by the researcher. He expressed he glances at key parts of the application but would not be able to ensure everything was the same on both.

Ms. Lund continues that it depends on how the researcher decides to save the VSAC application. The researcher can save the VSAC application in a way where it truncates all of the text. She advised she asks they save it in a new application so she can see all of the text. Attendees advised they did not know there were two versions of the saved application.

Dr. Dickey agrees with Dr. Schaeuble it is hard for a reviewer to crosswalk between VSAC and CPHS applications. Dr. Dickey does not like to do this process, advising Ms. Lund is more familiar with VSAC data. Dr. Dickey agrees with requiring researchers to attach their VSAC application and it's up to VSAC to determine if we approve what they're going to approve. If we look at it before VSAC does, then VSAC should be approving what we approve, not the other way around.

Dr. Delgado advised it is heard in theory, and the CPHS cannot tell VSAC how to do their job. Ms. Lund advises she has observed researchers submit different applications and it does not always get caught in the CDPH VSAC process.

Dr. Delgado suggests a presentation in a subsequent meeting of a de-identified research packet where Ms. Lund provides a tutorial for the Committee Members. Information can be provided about flags, things to look for, tutorials, and helpful hints. Ms. Lund agrees. Dr. Delgado questions the need for a motion since this is part of the CPHS admin workflow and summarized her thoughts. Ms. Lund advised the level of exposure is up to the comfort level of the reviewer.

Dr. Dickey inquired if a motion was required. Dr. Delgado advised there would be no motion unless someone disagrees. The expectation is changing as CPHS admin staff will no longer do the side-by-side application comparison since their actions were duplicative of the primary reviewer. CPHS admin staff will continue to confirm that letters and applications are attached to the protocol before it is sent to the primary reviewer.

Dr. Delgado confirmed the primary reviewer, depending on the risk of the project, the dataset, will do a comparison at the level they feel comfortable with as the primary reviewer. Ms. Lund is available to assist in the coming weeks before her presentation.

Dr. Schaeuble advised there will be differing levels of expertise and comfort. Confirming this will be done at the comfort of the primary reviewer.

G. Review and Approval of Meeting Minutes

February 2, 2024, meeting minutes.
Dr. Delgado announced that the meeting minutes are not ready for the March meeting, and this is only a vote on approving the minutes for February 2nd.
Motion: Dr. Dickey moved, and Dr. Hess seconded the motion to approve the February 2, 2024, meeting minutes.
Approve: Dr. Palacio, Dr. Ventura, Dr. Dickey, Dr. Ruiz, Dr. Bazzano, Dr. Dinis, Dr. Hess, Dr. Johnson, Ms. Lund, Dr. Schaeuble
Oppose: None
Abstain: None
Absent: Ms. Kurtural, Dr. Azizian

Total=10 In Favor-10, Opposed-0, Abstained-0

H. Projects with Reported Adverse Events and/or Deviations

1. Project # 2023-057 (Palacio)
   Title: Evaluating California's Guaranteed Income Pilot Program
   PI: Bridgette Lery, PhD
   Co-PI: Sarah Benatar, PhD
   Board Decision: Approved

Discussion:

Dr. Bridgette Lery, Co-Principal Investigator for the evaluation of California's guaranteed income pilot program, informed the committee about an adverse event related to their protocol. The incident involved a program partner mistakenly sending an email list of young people (all over the age of 21) to recruit for the program, which included names. All staff associated with the pilot sites were explicitly instructed not to send any personally identifiable information (PII) to the evaluators in any form. The email was sent through a city government agency's encrypted email system. Two individuals on the team who accidently opened the email, promptly reported the incident to the urban institution's Institutional Review Board (IRB). The IRB's protocol mandates the destruction of the data and emails involved and requires reporting to the IRB and subsequently to the Committee for the Protection of Human Subjects (CPHS).

Dr. Philip Palacio posed a question to the researchers regarding the adequacy of existing procedures to prevent similar incidents in the future. Dr. Lery confirmed that they believe the incident stemmed from a misunderstanding. Since then, they have reinforced the directive to the pilot sites and the California Department of Social Services (CDSS), emphasizing the prohibition on sending any PII in any form to the evaluation team.

In response to Dr. Palacio's inquiry about whether these procedures are documented or should be strengthened, Dr. Lery expressed confidence in their sufficiency. She noted that their IRB protocol explicitly states that no material containing PII should be shared.

Dr. Palacio then opened the floor to other committee members for questions regarding the adverse event. Dr. Delgado sought clarification from Dr. Lery, confirming that the email was indeed sent through an encrypted email system.

Motion: It was moved by Dr. Palacio and seconded by Dr. Ventura to accept researchers report of this adverse event, along with the corrective actions that researchers have implemented to prevent such occurrences in the future.
Approve: Dr. Palacio, Dr. Ventura, Dr. Dickey, Dr. Ruiz, Dr. Bazzano, Dr. Dinis, Dr. Hess, Dr. Johnson, Ms. Lund, Dr. Schaeuble
Oppose: None.
Abstain: None.
Absent: Ms. Kurtural, Dr. Azizian

Total=10 In Favor-10, Opposed-0, Abstained-0

2. Project # 2022-128 (Ruiz)
   Title: California Family Health Study (CFHS)
   PI: John Pugliese, PhD
   Co-PI: Sarah Kehl, MPH
   Board Decision: Approved

Discussion:

Dr. John Pugliese a scientist at California Department of Public Health is the PI for the California Family Health Study, which is a study of low-income California's who are eligible for the Cal fresh healthy living program. Dr. Pugliese was informed of a deviation to the protocol on February 5, 2024.

The research protocol is to mail out recruitment packages to recruit individuals into the study. The mailers are inserted into envelopes and mailed out. The adverse event that occurred on February 5, 2024, was concerning two recruitment packages that were labeled on the outside while did not match the letter inserted into the envelope. The letters do not provide any information in respect to how the household became eligible for participation. Rather, the letter is asking the participant to be involved in the study and providing information on how to participate in the interview, incentives for participation, and instructions for other materials such as a tape measure, food model booklet, and measuring cups.

After the review of the incident, it was suggested that it was due to potential inattention in filling the envelopes. The discovery of this event occurred during the follow-up recruitment process of making phone calls in respect to participants. One participant was contacted but was unable to have a discussion at the time about recruitment due to receiving a letter with someone else's name.

Since the incident Dr. Pugliese have reviewed the protocol with the staff employed by the Population Research Center (PRC) and emphasized on the importance of confidentiality. Some staff members were rotated out of doing that work and believe it's an isolated incident.

Dr. Juan Ruiz, the primary reviewer of this protocol, didn't have any additional comments, and mentioned the PI explained and managed the deviation in the protocol correctly.

Motion: It was moved by Dr. Ruiz and seconded by Dr. Dickey to accept researchers report of this adverse event, along with the corrective actions that researchers have implemented to prevent such occurrences in the future.

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

Total=10 In Favor-9, Opposed-0, Abstained-1

I. New Projects – Full Committee Review Required

1. Project # 2024-040 (Hess)
   Title: A Digital Intervention to Improve Skin Self- Examination among Melanoma Survivors
   PI: Sharon Manne, PhD
   Co-PI: Carolyn Heckman, PhD
   Board Decision: Approved Pending Conditions - Designee Review

Discussion:

Researchers have already developed an online intervention called MySmartSkin (MSS) and evaluated it in a randomized controlled trial for improving Skin Self Examination (SSE) and some protection, and other risk reduction behaviors for melanoma survivors. In this project, which is the second phase of the first study, researchers propose an innovative Type 1 hybrid effectiveness-implementation trial designed to enhance the effects of MSS and simultaneously assess key implementation outcomes as well as contextual factors important for scale-up in community and health care settings where melanoma survivors receive follow-up care. In the proposed study, the goal of the iterative process of enhancing MSS using stakeholder feedback and usability testing in Aim one is to improve Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) outcomes, which will be assessed in Aims two and three. In Aim two, the focus is on Effectiveness of the enhanced MSS, testing its effects on survivor-level outcomes including clinical outcomes In Aim three, the remaining RE-AIM outcomes will be addressed.

Participants will be identified and recruited through the New Jersey State Cancer Registry (NJSCR), California Registry of Greater California (CRGC), and social media (Facebook).

Researchers have already addressed the majority of the reviewers' comments and have uploaded copies of the surveys and interview script in the application. They also have provided detailed explanation about recruitment and enrollment process in the application.

Ms. Lund and Dr. Hess clarified that, by law, cancer registry data in California can only be released with the California Cancer Registry (CCR)'s approval. Therefore, the California Registry of Greater California (CRGC) cannot provide the data to researchers until it receives CCR's review and authorization. This is the reason a support letter from CCR is necessary.

Ms. Lund advised the researchers to directly request the data from CCR, given that CCR's approval is ultimately required for data release. The researchers explained their preference for CRGC stems from a history of collaboration and their comfort level with working with this particular registry.

Dr. Ventura asked the researchers to revise the wording in the “Screening” section of the application to accurately convey that information for individuals who opt not to participate in the study will not be shared or used further. This is to correct the current statement, which incorrectly suggests that their information will be shared and used further.

Additionally, Dr. Ventura noted that the consent form attached to the application is written at a reading level ranging from eighth to twelfth grade. She requested simplification of the consent form to ensure a consistent eighth grade reading level throughout all sections.

Motion: It was moved by Dr. Hess and seconded by Ms. Lund to grant the project a deferred approval 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. Hess.

1. **Securing a letter of support from the California Cancer Registry (CCR).**
2. **Exploring the possibility of adjusting the consent form's reading level to consistently match an 8th-grade level.**
3. **Correcting a typo in the application's screening section to clarify that information from participants who opt out will not be shared.**
4. **Distributing a copy of the California Cancer Registry (CCR) brochure to all participants.**

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

Total= 10 In Favor-10, Oppose-0, Abstain-0

2.	Project #	2024-043 (Azizian)
	Title:	Assessing Farmworkers' Understanding of their Rights and Benefits Related to Pesticide Exposure at the Workplace
	PI:	Ouahiba Laribi, PhD
	Co-PI:	Carly Hyland, PhD
	Board Decision:	Approved Pending Conditions - Designee Review

Discussion:

The overarching goal of this project is to assess how farmworkers access their rights and benefits when exposed to pesticides at the workplace, including knowledge of their benefits, which agencies to interact with, and the accessibility of materials and services from these agencies and to improve accessibility in this process.
Researchers will conduct semi-structured conversational interviews with farmworkers to explore how they access state rights and benefits and to assess farmworkers' knowledge on their rights and benefits.

Researchers plan to recruit a total of twenty individuals field workers who may be exposed to pesticide by working around or with pesticides, five for each of the four following groups:

1.Female farmworkers who are or have been pregnant while working in agriculture.
2.Pesticide handlers who prepare, load, or apply pesticides.
3.Fieldworkers working in the vicinity of pesticide applications or in treated fields.
4.Farmworkers who are experiencing symptoms that could be attributable to chronic effects of pesticides (e.g., cancers, chronic respiratory diseases, etc.).
Outreach for participation will be through study flyers distributed by community partners. Upon contact, researchers will verify participant eligibility, explain the study's objectives, and schedule the interview by asking the participants about their preferred time, date, and location for the interview.

Researchers will also ask a community-based organization to help them identify safe public spaces such as library or community centers for conducting the interview to mitigate risks like employer retaliation and confidentiality breaches. They will go over the consent form with the participants and ask whether they have any questions and if they are still interested in participating in the study, they will provide their oral consent, and then the researcher will sign the consent form and hand it to them for their record. Researchers don't take note and will collect audio recording. However, they will take note of the demographic questions, such as age and gender on paper. Once the interview is completed, the subjects will be thanked for their time, and receive a $50 gift cards to the local grocery store.

Researchers confirmed the risk of retaliation, and to limit this risk, they have offered options for safe locations, such as libraries. Researchers will require participants not to name people or sites, and they will delete those if they were given by mistakes.

Contact information will only be used for scheduling purposes and will be securely disposed of immediately after use. Audio recordings will be securely stored and deleted after transcription within three months. Demographic information collected on paper will be securely stored and then shredded after digital entry.

Researchers have already addressed the main comments provided by the primary reviewer of the study.

Researchers were required to consider some adjustments for the project application, including removing questions about immigration status from the interview script and adhering to UC Berkeley's IRB recommendations for verbal consent and separate handling of demographic information.

Dr. Schaeuble brought to the committee’s attention that researchers mentioned potential employer retaliation as a risk for the human subjects and wanted to make sure that's elevated and ensure that the board is attending to that issue.
The initial proposal submitted to the University of California, Berkeley (UCB), required researchers to review the consent form with participants, who would then sign and date it, with researchers storing the form securely. However, UC Berkeley suggested a modification requiring researchers to provide the form to participants, ensuring they have all the necessary information, and then obtain verbal consent to minimize additional confidentiality risks associated with handling the forms.
Dr. Bazzano requested further details on how researchers would validate participant consent in the event of a disagreement.
Dr. Dickey explained that a key reason for waiving written consent is if signing a consent form could be the sole means of identifying a participant, potentially causing them harm. He also suggested that obtaining a certificate of confidentiality from the National Institutes of Health (NIH) could be beneficial in this situation, as it would protect against having to disclose information. Furthermore, Dr. Dickey advised the researchers to seek a certificate of confidentiality from the NIH following approval from an IRB.
Dr. Ventura observed in the “Medical Service Risks” section of the application that the researchers anticipate no significant medical or physical health effects. They detailed how they would report any unexpected issues to CPHS. She recommended providing resources for participants who might experience distress during the interview from discussions about pesticide exposure, job loss, or fear of employer retaliation. Additionally, Dr. Ventura suggested that the consent form's language is too complex and recommended simplifying it for better understanding.
Ms. Lund pointed out that the “Limitations to Data Access” section of the application specifies that only the Principal Investigators (PIs) and approved study staff, naming Nancy Villasenor,

will access the data. She sought further details about the roles of other research staff listed in the application.
The researchers explained that Nancy Villaseñor, a health educator, will conduct all interviews, with another individual present to take notes. While other listed personnel may not access the raw data, they could review interview scripts. Dr. Hyland, identified as the Co-Principal Investigator, does not have access to raw data. She is the sole team member with a University of California, Berkeley (UCB) email address. Access to interview transcripts and any data files will be restricted to the Office of Environmental Health Hazard Assessment (OEHHA) in Oakland.
Dr. Darci Delgado, the Chair of CPHS, suggested that the researchers consider submitting an IRB reliance agreement between CPHS and the University of California, Berkeley (UCB). This would enable UCB to depend on CPHS's decisions, reducing the need for researchers to seek separate approvals from both IRBs. Once the reliance agreement is approved, UCB would be able to accept all decisions made by CPHS directly.

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

1. **As a suggestion, explore the IRB reliance agreement between CPHS and UC Berkley**
2. **As a suggestion, explore to look into a certification of confidentiality available via National Institutes of Health (NIH).**
3. **Simplify the consent form to decrease the reading level.**
4. **Add resources for participant specific to mental health, legal, and employment resources and retaliatory information.**
5. **Upload the revised consent form and questionnaire script in the application in IRBManager.**

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

Total= 9 In Favor-9, Opposed-0, Abstain-0

J. Full Board Continuing Review

None.

K. Amendments- Full Committee Review Required

1.	Project #	2021-219 (Dickey)
	Title:	Postmortem Analysis of Disorders and Development in Human Infancy Including Sudden Infant Death Syndrome
	PI:	Robin Haynes, PhD
	Co-PI:	
	Board Decision:	Approved Pending Conditions - Designee Review

Discussion:

Dr. Dickey observed that this project presents a unique situation for CPHS review. Typically, CPHS evaluates research projects based on the common rule, Information Practices Act (IPA), and various state statutes mandating approval. In 1989, a law was passed allowing county coroners to provide tissue samples for sudden infant death syndrome (SIDS) research without parental consent.

About two years ago the San Diego coroner was cooperating with Dr. Haynes. During that time the board of supervisors informed Dr. Haynes that they need to get approval from the Committee for the protection of Human Subjects (CPHS). Since Dr. Haynes was informed to reach out to CPHS, she reached out to CPHS, and it was approved without an informed consent from the parents since the law explicitly states that researchers do not have to get consent from parents if there is not going to be any visible deaf defamation of the child's body. Dr. Haynes provided a letter from the San Diego coroner that stated there would not be any visible deaf defamation of a child's body, and several letters from parents affected by SIDS patients. The letters from the parents stated that informed consent would be a barrier to research, and they wanted to do everything they would help with research. CPHS approved this initial submission of the project.

Since CPHS approved this project, the board of supervisors in San Diego have decided they want consent and will not allow the release of these tissues without consent. Dr. Haynes has submitted this amendment to CPHS with a proposal about how to get informed consent.

Ms. Lund suggested to Dr. Dickey if the committee provided a waiver of informed consent whether the board of supervisors would be satisfied with that approach. Dr. Haynes noted that the project was approved over a year and a half ago by CPHS with a waiver of informed consent and the board of supervisors informed Dr. Haynes they want consent and do not accept the waiver of consent from CPHS.

Dr. Haynes has submitted this amendment to the protocol to obtain consent from families since this research has been stalled for over three and a half years. Dr. Haynes team have been back and forth with the board of supervisors providing letters and petitions from family's and the board of supervisors still want consent.
Dr. Dickey suggested that CPHS approves a method of consent to satisfy the board of supervisors. It is noted by Dr. Dickey that this protocol is not being reviewed under the common rule and the consent will not have to comply with all the standards of the common rule.

Dr. Haynes provided some background to the consent forms that she has worked on with the assistance of the medical examiner. The medical examiner has worked closely with the board of supervisors to come up with this consent form that Dr. Haynes shares to the committee.

Two different consent forms were created for two different possibilities. The first consent form, Dr. Haynes' research team will work directly with life share donation services. Life share donation services has extensive experience talking to acutely breathed families. The issue with the first consent form is it would require consent within twenty-four to thirty-six hours after the infant's death, which is very difficult to do for everyone involved. Life share donation services is experienced in these situations and are on board to assist with the researchers obtaining consent in two different situations.

The first situation, if the infant qualifies for the tissue donation, Life share donation services would receive consent for the tissue donation. During this time, Life share donation services would present the tissue donation consent, and the request for SIDS research consent, signing two different consent forms.

The second situation which is the last option, one of the research staff will be training on getting consent from Life share donation services and then receive consent from the families internally.

The script would be the same regardless if Life share donations services or the research team obtained consent from the families.

Dr. Haynes shared the telephone script that would be used to gain consent from the families. Since the consent occurs over the phone, the recorded phone call is stored indefinitely since there is no actual signature the research staff would obtain from the families. Dr. Haynes notes that this have been approved by the council and the board of supervisors. The telephone script starts with an introduction and gathering some of the information from the families. If the families are willing to provide the tissue donation there would be a blurb ahead of the consent form regarding consent to SIDS research.

Dr. Dickey noted that this form is not signed by the partners, it is signed by the researcher obtaining the consent. This consent form is considered a waiver of written consent since the consent is being obtained over the phone.

Dr. Dickey pointed a section added to this consent form that was not in it before, that clarifies the tissues maybe be used in future research on SIDS or other related issues that the tissues could be used for, and whether the tissues are used to develop a commercial project product that the parents would not benefit financially. The other change to the consent form due to the state law is the section added where parents can opt in to have the tissues from the autopsies can be returned or should be returned to the parents for religious purposes.
Dr. Haynes acknowledged Dr. Dickey's hard work on assisting to improve the consent form. Dr. Haynes feels confident that this will be approved by the board of supervisors, she has been working closely with Dr. Campman, the medical examiner, who has been in contact with the board of supervisors.
Dr. Dickey turns over any questions or concerns to the committee members.
Dr. Ventura pointed the line stating that the participation in this research is voluntary and suggested that it should be moved up earlier in the consent form since this would be presented to families within hours of an infant's death and families in that situation are filling out multiple forms, they might feel obligated to opt in for this since it states research at the top of the form. Dr. Ventura feels strongly that it should be emphasized that this is still voluntary because this is being presented during a sensitive time. Dr. Haynes see's the value that Dr. Ventura brought up and will move the section stating that this research is voluntary to the top of the consent form.

Dr. Dickey noted he suggested separating the consent form from a generic organ donation/research form.

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

—Approval of the amendment with a new consent form. The new Consent form having a stipulation of moving the volunteering consent higher up on the form.

Approve: Dr. Dickey, Dr. Ventura, Dr. Ruiz, Dr. Hess, Ms. Lund, Dr. Palacio, Dr. Schaeuble
Oppose: None.
Abstain: Dr. Bazzano (bad internet connection), Dr. Dinis (not sure if this should be a common rule review due to the consent form), Dr. Johnson (personal reasons)
Absent: Dr. Azizian, Ms. Kurtural

Total= 10 In Favor-7, Oppose-0, Abstain-3

2.	Project #	2023-108 (Schaeuble)
	Title:	Evaluation of the Children and Youth Behavioral Health Initiative (CYBHI): Qualitative Data Collection and Analyses of Publicly Available, Deidentified Secondary Data
	PI:	Joseph Zickafoose, MD, MS
	Co-PI:	Dana M Petersen, MA, MPH, PhD Matthew Niedzwiecki, PhD Amanda Lechner, MPP Cara Orfield, MPP Gina Sgro, MPH
	Board Decision:	Approved Pending Conditions - Designee Review

Discussion:

Researchers from Mathematica are conducting an evaluation for the California Health and Human Services Agency (CalHHS) on the Children and Youth Behavioral Health Initiative. This mixed-methods evaluation includes analyzing quantitative outcomes using secondary data, reviewing documents on grant programs funded by the initiative, and collecting primary data through interviews, surveys, and focus groups. The researchers have submitted an original project application and two amendments. The original application covered the analysis of publicly available data sources and included key informant interviews with state policymakers and agency staff across various departments within CalHHS.

In the first amendment researchers requested approval for adding a statewide survey of caregivers, youth and young adults about their experiences with behavioral health services in California.

In the current amendment, researchers have requested approval to add new quantitative and qualitative data collection in nine California counties to help us gather additional data to answer aspects of the original research questions. They plan to conduct a web-based Network and Ecosystem Experiences survey (NEES) and key informant interviews with representatives of child- and youth-serving agencies and organizations in each of nine counties.

Dr. Schaeuble clarified that researchers have already addressed most of his comments with only a few minor changes remaining that will be outlined in the final motion.
Dr. Schaeuble suggested that researchers submit any future amendments as new projects to avoid the complexities of integrating them into the existing, approved research activities. He also mentioned that he had shared an article with the Principal Investigator (PI) of the project titled "Careless Responding" that could be helpful for the researchers, particularly in managing the implications of haphazard responding among paid online participants, as noted in their first amendment. The article discusses potential outcomes and methods for addressing these issues. Dr. Schaeuble found it interesting and believed it could be beneficial, prompting him to

share it. The researchers have confirmed that the article has been helpful and expressed their appreciation for his sharing it with them.

The researchers indicated that one of the nine California counties originally listed for data collection has declined to participate. They will replace it with another county. It was recommended that this change be included in the current amendment along with addressing other required revisions.

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

1. Replace all documents showing track changes with clean copies for the entire project application.
2. Uncheck the "No identifiable materials" option in the "HIPAA Identifiers" section to ensure consistency throughout the application.
3. Remove the name of the previously added research staff from the "Personnel Information for Amendment" page.
4. Uncheck the "Not Applicable" option in the “Vulnerable Populations” section of the application.

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

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

L. Second Review Calendar

None.

M. 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 (29)

N. 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 (21)

N1. 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 (107)

O. Amendments – Projects with Revisions Approved Through Expedited Review

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

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

None.

Q. Exemption/Not Research Approvals

Total Project Count (8)

R. Final Reports

Total Project Count (2)

S. Public Comments

Dr. Schaeuble provided a comment regarding providing a statement on if you oppose or abstain on voting for a project. Dr. Schaeuble recognized that it is in the policies and procedures but believes that it should not be mandated that you need to present your reasoning for why you oppose or abstain on a project. Dr. Delgado suggested that he do what Dr. Dickey did about the adverse events and propose new language to the committee that will be voted on for changing that part of the policy and procedures.

Dr. Schaeuble asked if the other committee members would be interested in reading a research article regarding the impacts of haphazard/careless responses to surveys and questionnaires.

Dr. Dickey mentioned it is very hard to hear some people over zoom and he doesn't know the solution but wanted to bring it to our attention.

T. Next Meeting

The next CPHS meeting is scheduled to be held on Friday, June 7, 2024.

U. Adjournment

This meeting was adjourned at 12:35 P.M. on April 5, 2024.