State of California—Health and Human Services Agency
Committee for the Protection of Human Subjects

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

GAVIN NEWSOM
Governor

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

Friday, April 25, 2025
8:30 a.m.

Zoom:
CPHS April 25, 2025, Full Committee Meeting

Meeting ID: 161 969 2875
Passcode: 618183

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: 161 969 2875

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
Maria Dinis, PhD, MSW
Philip Palacio, EdD, MS
Juan Ruiz, MD, DrPH, MPH

Alternate Member
Millard Murphy, JD
Lois Lowe, PhD

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
Maria Ventura, PhD
Laura Lund, MA

Committee Members Present Remotely:

Philip Palacio, EdD, MS
Juan Ruiz, MD, DrPh, MPH
Maria Dinis, PhD, MSW

CPHS Staff Present in Person:

Agnieszka Rykaczewska, PhD
Sussan Atifeh
Karima Muhammad
Nicholas Zadrozna

Cal HHS Present in Person:

Jared Goldman
Maggie Schuster

Principal Investigators and Associate Investigators In person:

Michael Valle
Jame Yi
Chris Krawczyk

Also, Present Principal Investigators and Associate Investigators Remotely:

Jiajuan Liu
Megan Mahoney
Regan Foust
Evan White
Linda
Angelique Lastinger
Erika bustamante
Lina Remmy
Lauren Wallner
Megumi Okumura
Denise Modjeski
Wade luele
Matthew la Rocque
Laurn walker
Kimberly miller
Lisa Shugarman
Cindy Bui
Tyson Wright
Xueyin yang
LeeAnn McCabe

Alina Xu
Kay Chang
Olivia Burdon
Ryan Buckley
Adrian Aryarad
Michael Calle
Dionne Evans-Dean
Chris Craig
James Yi

A. Welcome

a) Chair Updates

Dr. Hess called the meeting to order. Reminding remote committee members to have their cameras turned on during the meeting. Sussan Atifeh took role call and confirmed establishment of quorum for the meeting. Dr. Hess informed the committee that the considerations for Information Practices Act (IPA) review will continue to be tabled as the Governor's Office has requested additional time to review.

B. Administrative Update

A) Update on recruitment for new CPHS members

Dr. Rykaczewska, the CPHS Administrator, announced that with the departure of Dr. Delgado and Dr. Bazzano that CPHS is recruiting new members for CPHS, and the requirements are listed in the policies and procedures.

Dr. Rykaczewska suggested that if anyone is interested in joining the committee that they submit a cover letter, resume, and a list of references to the CPHS inbox at cphs@chhs.ca.gov.

Dr. Rykaczewska informed the committee that the nominations must be knowledgeable in the areas of research that CPHS reviews. Since CPHS reviews such a diverse range of topics, nominations do not need to be an expert in every topic, but at least some of them. While knowledge of general scientific research is important, the committee is required to have at least one member whose primary area of expertise is non-scientific.

CPHS is looking to find some nominations that have knowledge in the data privacy laws and data security. As well as experience working with vulnerable populations.

Committee members review a range of 15 to 25 projects every two months and attend the CPHS full board meetings in Sacramento.

More information on the criteria used to prioritize candidates and the members duties can be found in the Policies and Procedure document on page 9 and 10. The CPHS Policies and Procedures are located on the CPHS website, and a link has been placed on the homepage notifying that CPHS is recruiting members at this time.

Dr. Rykaczewska touched on the process of recruitment. She explained that she would pre review the applications and compile them together for the Chair and Vice Chairs review. The

Chairs would then prioritize a list of candidates and submit them for the California Health and Human Services (CalHHS) Secretary's consideration. Lastly the CalHHS Secretary would appoint the members, and they would be sworn into the committee.

Dr. Rykaczewska noted that the committee does take nominations on an ongoing rolling basis, that CPHS will begin its review on May 5, 2025, to compile a list of nominations for the Chair and Vice Chair to review. She requested if anyone had additional questions regarding the recruitment process to email cphs@chhs.ca.gov.

C. Discussion of Data Sharing Guidance

Dr. Hess invited Attorney Maggie Schuster to provide some information to the committee on the updated data sharing guidance and the role of the board.

Attorney Schuster noted she was not present for the previous board meeting but have been filled in on some of the questions that were brought up. One of those questions brought up was if the committee should require researchers to submit Certificates of Confidentially (COC) in the CPHS application. The COC have been issued by the National Institute of Health (NIH) and the purpose of the certificate is to protect the privacy of research participants.

Attorney Schuster noted when looking at the IPA, one of the requirements under CPHS review is to determine that researchers have provided a sufficient plan to protect from improper disclosure. However, there is no requirement in the statue that researchers must submit a COC as part of the review.

Attorney Schuster suggested if CPHS starts to require a COC to be submitted as part of the review, it has a risk of being considered an 'underground regulation' and CPHS would be open to a greater legal risk. She clarified that while the committee has the authority to assess whether researchers have an adequate plan to protect Personally Identifiable Information (PII), the COC itself should not be a required element or factor in the committee's evaluation.

Dr. Azizian asked for clarification about underground regulations. Attorney Gared Goldman explained that any rule that applies broadly to researchers, not just internal procedures, must be officially promulgated as a regulation. This is a long and expensive process, but it is the only way to make such rules enforceable. Otherwise, the rule could be challenged in the Office of Administrative Law (OAL) and considered unenforceable. Attorney Goldman recommended that instead of adopting broad rules, the committee should make requests on a case-by-case basis. He also mentioned that if CPHS wanted to require a standard assurance for all projects, that would be considered an underground regulation unless it is properly promulgated.

Ms. Lund asked if committee members could require a university to guarantee that data wouldn't be released under any circumstance when the nature of the requested data is very sensitive. Mr. Goldman said they could require that data not be further disclosed except as required by law, but they couldn't force anyone to ignore a legal order like a subpoena.

Ms. Lund expressed serious concerns about releasing personally identifiable information, including information about place of birth if it is outside of the country, abortion, and women's reproductive health. Attorney Goldman encouraged CPHS review projects on a case-by-case basis. Attorney Goldman suggested that CPHS can decide in reviewing a project that CPHS can limit the disclosure of data or the use of the data by the researchers of that data.

Dr. Dickey asked about state law and abortion data and where there is a lack of state law to empower Institutional Review Boards (IRBs). Attorney Goldman readvised considering the research projects on a case-by-case basis. The law that requires IRB review for the disclosure of abortion related data is in the Confidentiality of Medical Information Act (CMIA) and CMIA applies to providers, health plans, contractors, employers, etc.

Ms. Lund asked if CPHS could require an out-of-state researcher to partner with a California institution to keep data in California. Mr. Goldman said yes, the committee has flexibility and can be creative in protecting people's data and adding reasonable conditions. On highly sensitive projects, the committee was encouraged to reach out individually to legal counsel for help.

Dr. Hess raised the release of data sets that contain abortion/immigration data that is not the focus of the research project. CPHS does not currently ask, for example, HCAI scrub the data of ICD9/10 codes before it is released. Can CPHS require this of limited data sets? Attorney Goldman suggested that CPHS already requires this ask for limited data sets and encourages CPHS communicate with the researchers to limit the privacy disclosure to the information the researchers actually need for the research protocol.

Dr. Rykaczewska advised researchers provide justification at a variable level but not necessarily at the value of the variable so in requesting codes, the researchers may need some of the ICD codes but not necessarily all of them. Dr. Rykaczewska suggested taking it a step further than our current practices. Dr. Dickey advised CalHHS Departments have a responsibility to provide data that is clean.

Dr. Dickey returned to the subjects of COCs. Dr. Dickey informed the committee that NIH will not give certificates for databases which is stated on the NIH website.

No in-person or virtual comments from board members of the public.

D. Review and Approval of Meeting Minutes

Dr. Hess asked if there were any comments or public comments on the meeting minutes from November 8, 2024, meeting minutes.

No comments or public comments were made.

MOTION: It was moved by Dr. Dickey and seconded by Ms. Lund to approve the November 8, 2024, Meeting Minutes.

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

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

E. Projects with Reported Adverse Events and/or Deviations

1. Project # 13-02-1077 (Lund)
Title: Longitudinal Study of Hospital Outcomes for California's Children

PI: Jennifer Rienks, PhD
University of California, San Francisco
San Francisco, CA

Discussion:

During the discussion, Dr. Hess stated for the record that Doctor Dickey would be stepping out due to a Conflict of Interest.

Ms. Lund explained that the adverse event involved a longstanding research project—originally approved back in the nineties—that had been ongoing for many years and used birth data with Personally Identifiable Information (PII) linked to other data. She noted that the project had expired and that, after multiple unsuccessful attempts to get a continuing review or an update on the project status, a phone call made by the committee admin revealed that the Principal Investigators had left the institution without reporting or submitting an amendment, and they had retained the data.
Ms. Lund described that the data were stored on a standalone computer in the Co-PI's home, which was not accessible to the Internet and was shut down during storage, and that, by agreement with the California Department of Public Health (CDPH), these data were later moved to a secure storage facility at UCSF—with Dr. Rykaczewska, CPHS administrator, clarifying that the actual computer was physically moved to a secure UCSF storage facility rather than a network.
Ms. Lund stated that the data belongs to CDPH and that CDPH had told the investigators they must shut down the project, with a closure report pending. The information was to be presented to the Board to see if anything should be included in that report. Additionally, UCSF intended to use these data to continue a similar project by identifying a new principal investigator who could submit a new project application and obtain approval from both CDPH and the committee. However, the project under review for this adverse event would be closed.

Dr. Rykaczewska added that in the meantime UCSF has submitted an updated continuing review application purely for the storage of the data in the meantime, while we resolve and transition to a new project. They do have approval currently to store the data.

Ms. Lund explained that continuing review is time limited and that the project would no longer exist after June 1st. At that deadline, the data must either be transferred to the new project or destroyed. She expressed serious concern about the adverse event because the principal investigators had been out of compliance with the CDPH data use agreement and lacked an approved CPHS protocol, yet they retained the data. She noted that this behavior potentially violated State law—which does not allow unauthorized people to access secure birth data and could be a misdemeanor—and stressed that the committee relies on researchers to follow the rules to keep the data safe. Although the approved protocol showed that the data had been stored safely, Ms. Lund questioned why the data should have been stored at all and then asked the research team to explain how and why the situation occurred, and to provide any additional information about the adverse event.

Dr. Remy mentioned that the reason that they had to put the data on the encrypted computer that she was using was that the contract with the State of California had ended, and she had to download the data from the server at the University of California in order to protect it. Data had been on her computer until they hired some programmers, and then, when the programmers were gone, they had no money to keep it back on the server, and they decided to move the data back down to her highly protected computer. Then she closed up the computer and had to buy a

new computer because they were no longer on the server, and she did not want to use the computer that had the confidential data on it. She added that the computer with sensitive data was never used after the data was downloaded from the UCSF server back to the computer, where it had always been before, when they had so many programmers working with them. She also mentioned that it was always approved to be saved on my computer, and then for a few years it was also on the server at UCSF which she moved it back. Dr. Remy emphasized that the computer was never used after the data was downloaded from the UCSF server, and she stressed that if anything was done wrong, it was not her intention, as she believes the data is a national treasure that must be protected and used.

Ms. Kurtural asked if the data were ever on a laptop and how long they remained on Dr. Remy's standalone desktop. Dr. Remy clarified that the data were never on a laptop, that it took about a week and a half to download all the data from the server, and that she downloaded it at the end of August 2024, after which the data were stored at UCSF.

Dr. Ventura asked Dr. Remy to clarify whether programmers had accessed the data, to which Dr. Remy confirmed that access occurred only when the data was stored on the UCSF server. When Dr. Ventura inquired whether those programmers were approved under the research protocol, Dr. Remy affirmed that each individual had been officially approved as part of the research team. Ms. Lund then pointed out that the protocol was expired at that time. Dr. Remy responded that while the protocol was expired, the programmers had already left as of June 30th, and from that point forward, only she and Co-PI Jennifer Rienks remained involved.

Ms. Lund emphasized that with an expired protocol, no one—including Dr. Remy—should have been handling the data. Dr. Remy explained that she downloaded the data from the server onto her computer solely to save it and that it was not used in any way after the download.

Ms. Lund expressed concern over Dr. Remy's statement about saving the data, explaining that without a valid CPHS protocol, the action was out of compliance with both CPHS regulations and the data use agreement with CDPH, since those agreements required an approved protocol for handling the data. She stressed that, beyond violating institutional agreements, the action was also potentially out of compliance with State law. Ms. Lund asked why Dr. Remy had not reported the situation to CPHS or CDPH. Dr. Remy replied that she had not realized this was an issue and explained that she and Jennifer Rienks were actively searching for a new principal investigator, as both were retiring, and that they had now found one.

Ms. Lund pointed out that CPHS had sent multiple requests asking about the project's status and continuing review, including a letter in August requesting a response, but they had not received any replies. Dr. Remy stated that she had not received these communications because she no longer had access to a UCSF email. Dr. Agnieszka Rykaczewska confirmed that the UCSF email was the only contact information submitted with the research protocol. Dr. Hess then asked whether these emails had also been sent to the responsible official, and Dr. Rykaczewska confirmed that they had. Dr. Mahoney, the responsible official, stated that she could not confirm receiving an email about the matter in August but acknowledged that she began receiving emails this year. While she was listed as the responsible official at that time, she did not recall seeing any emails concerning the project until recently.

Dr. Ventura raised concerns about the security of the data once downloaded to a PC, stating that there was no way to verify whether it had been accessed. Dr. Remy insisted that the computer was secure, clarifying that it was not her personal PC but belonged to the University of California. She explained that access required two passwords, that the computer was always

turned off when she was not present, and that no one besides her had worked on it. Dr. Ventura emphasized that without login tracking or verification systems, there was no way to confirm if others had accessed it. Dr. Remy maintained that the data remained protected and was never accessed by anyone else.

Dr. Azizian raised concerns about whether there had been a breach of confidentiality beyond the compliance issues. He questioned if the researchers recognized that programmers had accessed and transferred the data at a time when there was no longer formal approval, asking whether this constituted a violation. Dr. Remy responded that she was the only person who transferred the data and that by the time she moved it, all programmers were gone.

Dr. Ventura asked if UCSF had officially approved the download, and Dr. Remy admitted that she and Jennifer Rienks decided on it themselves without formal authorization. She added that once she downloaded the data, UCSF disconnected her access, and no one at UCSF could view it.

Dr. Rykaczewska said that CPHS sent emails in August and October 2024, telling the research team, including Dr. Mahoney, that their approval had expired and needed to be renewed. The October email also told them to stop all research until they submitted a continuing review. She confirmed that Dr. Mahoney was included in both emails.

Dr. Mahoney admitted she got a lot of emails as department chair and usually assumed the principal investigators would handle things. Since Dr. Rienks was still working at UCSF at the time, she thought Dr. Rienks would take care of it. She apologized for any extra work this caused for CPHS staff and thanked them for their efforts.

Ms. Lund asked who was responsible if the Responsible Official (RO) of the project didn't take action. Dr. Mahoney agreed that she should have stepped in and explained that Dr. Rienks was going through a difficult personal situation, which may have caused delays. She said the situation was a series of mistakes and that someone should have taken responsibility.

Ms. Kurtural stated that UCSF should immediately investigate whether a data breach occurred and determine if notifications need to be sent. Ms. Lund agreed, noting that when confidentiality is breached, researchers are responsible for notifying individuals whose data might have been compromised. She emphasized that several protocols were not followed, including downloading the data without approval despite the project's expiration. She suggested requesting an audit to review access to the data and how it was downloaded, as it appeared the download might not have been encrypted or properly secured. Ms. Kurtural added that UCSF's IT team should be alerted.

Ms. Lund expressed uncertainty about how to fix the situation and invited suggestions from the committee. Dr. Rykaczewska mentioned that Dr. Okumura had been identified as the new principal investigator, should the work continue, and noted that she was available to discuss the new project application.

Dr. Ventura asked whether CDPH had been notified, similar to UCSF IT Security. Ms. Lund confirmed that CDPH was aware of the situation and had been working closely on the resolutions discussed. She explained that CDPH had approved temporary secure storage at UCSF until a solution was found for the next project. Dr. Ventura asked for confirmation that no one should be accessing the data at this point. Ms. Lund confirmed, emphasizing that the data was only being stored and was under continuing review approval.

Ms. Kurtural suggested that UCSF should agree to an investigation and provide necessary information, noting that details are available online. Ms. Lund confirmed that a report would be sent back to the committee. She emphasized that legacy projects often face challenges related to security and changes in the law, which require careful review. She explained that because the original project was approved a long time ago, laws and security requirements have changed, and the new project application would likely need adjustments to meet current standards. CDPH/VSAC would be involved in the approval process, as they are responsible for ensuring compliance with updated laws. Some aspects of the old project may no longer be allowed under new rules, and security protocols that were previously approved might not meet today's standards.

Ms. Lund then asked Dr. Remy if she or Dr. Rienks had any open research projects with the committee, and Dr. Remy confirmed that they did not. Ms. Lund stated that, given the issues with this project, it was important for UCSF to be aware of the situation and to remain watchful for similar problems in other projects.

Dr. Dinis asked what should be done if the investigation finds no breaches of confidentiality. Ms. Lund said there might not be anything the committee could do in that case. She noted that if Dr. Remy and Dr. Rienks still had open projects, she would ask the committee to review them, but since they do not, there was nothing further to discuss.
There were no comments from the public.

Motion: It was moved by Ms. Lund and seconded by Ms. Kurtural to accept the adverse event report. The Committee will alert immediately the chief information security officer at UCSF, will describe the problem to them, and will ask them to commence an investigation to determine if there was a security breach and if any personally identifiable data were exposed, to take action to notice individuals affected and report that incident to federal and state authorities as required by law, and to report back on their findings to CDPH and CPHS.

Approve: Ms. Lund, Ms. Kurtural, Dr. Azizian, Dr. Dinis, Dr. Johnson, Dr. Palacio, Dr. Ruiz, Dr. Schaeuble, Dr. Ventura.
Oppose: None.
Abstain: None.
Absent: Dr. Dickey due to a due to a Conflict of Interest.

F. New Projects – Full Committee Review Required

1. Project # 2025-004 (Johnson)
Title: Evaluation of Community Response Initiative to Strengthen Emergency Systems (C.R.I.S.E.S) Act Grant Pilot Program
PI: Catherine Dun Rappaport, MPP
Social Finance–Boston
Boston, MA

Discussion:

Dr. Johnson, the primary reviewer, explained that the study had undergone several iterations before reaching its current form. The research involved two main types of data: service delivery

data collected by the California Department of Social Services (CDSS), which was mandated by state law, and survey data gathered by Social Finance with participant consent.
Mr. La Rocque, representing Social Finance, provided an overview of the study. He explained that the research stemmed from the California Crises Act (AB 118), which aimed to support community-based crisis response programs as alternatives to law enforcement involvement. The study sought to assess client satisfaction, the effectiveness of pilot programs, and the potential for expanding community-based emergency response services. Service delivery data was gathered during crisis response incidents, including wait times and services provided. Social Finance accessed this data through CDSS and requested a HIPAA waiver to ensure compliance. Meanwhile, survey data was collected directly from individuals receiving crisis response services, with participants providing written consent through Qualtrics.
Dr. Johnson noted that the service delivery and survey data sets were separate and not linked. She found no significant issues with the HIPAA waiver request and considered the consent form clear and straightforward. She identified minor inconsistencies in the application, such as unclear details on whether participant contact was conducted via email or text, and the lack of clarity about whether data collection was happening through Microsoft Forms or Qualtrics. She suggested clarifying data transfer methods in the proposal.
Dr. Dickey brought up concerns regarding the formatting of the HIPAA waiver approval, emphasizing that it should specify the exact data variables being granted under the waiver, including name, telephone number, and email address. He pointed out that previous CPHS approval letters had simply granted a HIPAA waiver without listing the specific variables.
It was clarified that the HIPAA waiver should apply only to service delivery data, not survey data. It was also stated that only the data fields that the research team did not obtain themselves, but are getting, should be specified in the waiver. Additionally, it was noted that CPHS is responsible for approving the waiver only for those variables that were specified in the protocol.
There were no public comments during the discussion.

Motion: It was moved by Dr. Johnson and seconded by Ms. Lund to grant the project 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. Johnson.

1. **Please modify the inconsistencies for confirming how and when information is exchanged for the survey data.**
2. **Please clarify that the data are being collected in Qualtrics and not Microsoft forms.**

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

2. Project # 2025-052 (Ventura)
Title: California Long Term Services and Supports (LTSS) Financing Initiative
PI: Lisa Shugarman, PhD
NORC at the University of Chicago
Chicago, IL

Discussion:

Dr. Ventura, the primary reviewer of the project, initiated the discussion by asking Dr. Sugarman to provide a brief summary of the project. Dr. Sugarman from the National Opinion Research Center (NORC) at the University of Chicago explained that the study involves two surveys, with the current discussion focusing on the first. The survey will use NORC's AmeriSpeak panel, which has been operational for many years and allows participants to consent to different surveys throughout the year. This particular survey targets California residents aged 50 and older and will explore their concerns regarding retirement, long-term care planning, and financing. It is part of a larger project funded by the California Department of Aging (CDA) in collaboration with the University of Massachusetts, Boston, and CDA. Participants in the survey will be given a $4 incentive and can choose not to answer any specific question. The second survey will be submitted as an amendment to this IRB request when it is ready.
Dr. Ventura noted that the submission indicated that participants consented to be part of the AmeriSpeak panel and receive survey invitations. However, she considered these two separate issues, stating that joining the panel is one matter while consenting to participate in research through the survey is another. Additionally, she raised concerns about the reading level of the consent language, which she said was at a 12th-grade level. When she asked for the language to be simplified, she was informed that changes could not be made because the consent had been approved ten years ago.

Ms. McCabe clarified that the panel's informed consent had been modified over the last decade and was meant for respondents joining the panel. Some clients require separate informed consent for their specific surveys, while others work with NORC's IRB to obtain a waiver. She added that they were open to incorporating an informed consent process for this survey specifically, including a brief introduction and reminders about data privacy.

Dr. Sugarman explained that the consent language provided in their submission referred to participation in the panel, not the survey itself. The survey consent language is embedded in the survey, allowing respondents to opt in or decline participation. Since the participants are already members of the panel, the concern should be about whether the consent language in the survey is sufficient. She mentioned that they could add additional language at the beginning of the survey to ensure clarity, but they would not be revising the consent process or language used for joining the panel.

Dr. Shugarman explained that the consent language is embedded within the survey itself, meaning that participants agree to participate by continuing with the survey. She stated that if the board felt the consent language needed to be strengthened at the beginning of the survey, additional language could be added. However, she emphasized that the consent process for joining the AmeriSpeak panel cannot be modified for this project because it is governed by a different IRB. She clarified that they are not adding new panel members for the survey, but rather working with individuals who have already consented to be part of the panel.

Dr. Ventura acknowledged this distinction and reiterated that the board was only reviewing the consent process for participating in the survey itself, which she felt was insufficient. She mentioned that while the language included a statement that participants could choose not to answer specific questions, it did not provide a description or summary of the types of questions they would be asked, the estimated time to complete the survey, or the participation incentive. She suggested that more details should be included to help participants understand what they are agreeing to.

Dr. Ventura clarified that one suggestion was to include a description of the topics covered in the survey, such as healthcare and retirement health concerns, to ensure transparency. She

pointed out that the email and phone scripts did not include details about the expected survey length, or the questions participants would be asked, suggesting that this information should be provided.

Dr. Schaeuble asked whether participants in the survey were required to decline twice if they did not want to answer a question.
Dr. Dickey read the existing survey language, which states that if a participant skips a question, they will receive a prompt asking them to complete their response. Dr. Schaeuble noted that requiring participants to confirm their decision to skip a question adds a burden and should be clearly stated in the consent information. He also suggested identifying any potentially sensitive topics within the survey at the beginning along with examples to prepare participants for what they might encounter. He mentioned that typically, participants should be able to decline a question without additional pressure to respond.
Ms. Lund noted that it was designed to prevent participants from unintentionally skipping a question. She commented that this situation was somewhat unusual because the research subjects are already familiar with participating in studies, meaning they have experience and understand the process. She suggested that the burden on participants may not be as significant as it would be for individuals new to research studies. Dr. Dickey agreed with her assessment.
Dr. Dickey then asked about the AmeriPoints incentive mentioned in the application. Ms. McCabe, a member of the research team, explained that AmeriPoints serve as the reward system for survey participants, with 1,000 points equivalent to $1. Participants can redeem their points for electronic gift cards and other options. She added that panelists regularly take surveys and are invited to participate multiple times a year. If they have any questions about the process, there is a full support team available to assist them.

Dr. Schaeuble asked whether it was common practice in surveys to require participants to confirm their decision to skip a question before proceeding. Ms. McCabe responded that while AmeriSpeak conducts many surveys each year, prompts are generally used for questions that are critical to the research. She explained that although prompts are not included in every survey, this particular survey does include a prompt for every question. She noted that participants are informed at the beginning of the survey that they will see prompts but can move forward, and they are always given the option to end the survey at any time if they choose.

Dr. Shugarman emphasized that the survey design was created based on the request of the California Department of Aging and the University of Massachusetts (UMASS), Boston.

Dr. Ventura pointed out that Spanish-language materials had been submitted with the application but had not yet been reviewed. She stated that once revisions to the consent form were finalized, the Spanish-language materials would be reviewed by Dr. Ruiz.

Dr. Ventura then raised another issue regarding the data storage and transfer process outlined in IRBManager. She noted that identifiers would be stored separately from analysis data and that only de-identified data would be sent to UMASS. However, she observed that this was the first mention of UMASS in the application and that no research personnel were listed from UMASS. She asked for clarification regarding UMASS's involvement and why the data was being sent to them.
Dr. Shugarman explained that UMASS would receive the de-identified data and serve as both part of the larger research team and as the program office for the California Department of

Aging. She stated that UMASS would manage the project funds and perform analysis on the data, though their work would be separate from the role of NORC.

Ms. Lund then questioned whether the current protocol was structured for data collection only and did not include provisions for data use or analysis. She emphasized that if UMASS planned to use the data for research, the protocol should also describe how the data would be analyzed and used.
Dr. Azizian suggested that this should be acknowledged in the consent form. Ms. Lund reiterated that UMASS's involvement in research should either be added to this application or submitted as a separate application for approval.

Dr. Shugarman explained that the analysis process involved two steps: NORC would conduct an initial descriptive analysis, which could be included in the application, while UMASS would perform additional analysis that was outside NORC's involvement. She suggested separating the application into two parts to expedite the approval of the data collection, given that the project was already behind schedule due to IRB review delays. She also raised the question of whether the nature of the data, which belongs to AmeriSpeak rather than the California Department of Aging, should be taken into consideration.

Ms. Lund stated that her concern was the release of data to UMASS and suggested approving the protocol for data collection but withholding approval for data release until further documentation was submitted. Dr. Dickey agreed and proposed that an amendment could be submitted separately for data transfer to UMASS. Dr. Ventura also expressed support for an amendment, emphasizing that the current approval should apply strictly to data collection, while plans for data transfer and analysis at UMASS would need further review.

Dr. Shugarman asked if the amendment should be submitted by UMASS Boston, but Dr. Dickey clarified that the amendment should be submitted by her, with UMASS listed as research staff. Dr. Ventura added that the amendment should specify who would receive the data, who would be responsible for it at UMASS, and details about data security before transferring it.

Dr. Hess questioned whether NORC would remain responsible for data security after transferring the data or whether UMASS should assume responsibility. She suggested notifying the California Department of Aging about the involvement of UMASS. Ms. Lund noted that if UMASS were listed as Co-PI, they would be responsible for data security. She acknowledged that requiring a new application for UMASS could be complicated but stated that she wanted a way to make UMASS the responsible party to ensure accountability.

Dr. Rykaczewska, CPHS Administrator, clarified that the board could approve the data collection portion now while requiring an amendment for UMASS's involvement in data analysis as a second phase. Dr. Dickey affirmed that UMASS might still need to seek approval from their own IRB separately. Dr. Schaeuble then suggested that survey participants should be informed at the start of the survey that their de-identified data may later be analyzed by UMASS, as they would not have the opportunity to consent to this after data collection.
Dr. Dickey noted that this situation would involve a waiver of written informed consent while still ensuring participants were informed.

No comments were provided from the public.

Motion: It was moved by Dr. Ventura and seconded by Dr. Azizian to grant a deferred approval, one-year, minimal risk, and waiver of written informed consent pending the following specified

modifications to the consent section of the survey, which require expedited review and approval by a CPHS subcommittee of Dr. Ventura and Dr. Ruiz—for the Spanish-translated documents only. No approval for data transfer until an amendment is submitted and approved.

1. More description of the types of questions being asked, length of time to complete the survey, the incentive they will receive, language around University of Massachusetts potential involvement for data analysis.
2. Spanish review of all materials is pending.

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

3. Project # 2025-041 (Dickey)
Title: Health Care Payments Data (HPD) System Operations
PI: Dionne Evans-Dean, MHA
Department of Health Care Access and Information (HCAI)
Sacramento, CA

Discussion:

CPHS Chair Dr. Hess noted that the committee was reviewing the database under the Common Rule. The HCAI/HPD team introduced themselves, including key personnel involved in data management, cybersecurity, analytics, and project oversight.
CPHS Vice Chair Dr. Dickey, the primary reviewer, acknowledged the extensive review process that had already taken place. He emphasized that the committee is not used to reviewing databases or registries, mentioning past instances such as the Parkinson's registry. He referenced guidance from the Office for Human Research Protections (OHRP) issued in 1997, which outlines IRB responsibilities in approving protocols for data repositories. While this guidance originally focused on tissue depositories, it also applies to data registries.
Dr. Dickey explained that registries should be reviewed by the IRB of the institution, but subsequent data releases are reviewed by the receiving institution's IRB, per OHRP guidance. However, the Information Practices Act (IPA) requires additional review of releases. He stressed the importance of ensuring compliance with current review standards for registries, including approval of policies and procedures and handling the informed consent process.
Dr. Dickey raised concerns about certain sensitive details that cannot be shared publicly, as doing so might compromise the registry's security. He identified two major issues requiring discussion: registry policies and procedures and the informed consent process. With this introduction, he invited the team to proceed with their discussion.
Mr. Michael Valle provided an overview of the Health Care Payments Data (HPD) System, explaining its role in consolidating healthcare claims for research and analysis. The database, established by AB 80, aims to improve cost transparency and support public health initiatives. He highlighted rising healthcare expenses in California, emphasizing the importance of data aggregation to reduce disparities and enhance oversight. The HPD compiles 1.3 billion healthcare claims annually, standardizing records across Medi-Cal, Medicare, and commercial insurers. Data security is ensured through the HCAI secure data enclave, allowing controlled access and remote deletion post-project. Mr. Valle concluded by passing the discussion to James Yi, HCAI counsel, to outline key project considerations.
Ms. Lund asked about how HPD research and analysis would be used for policy decisions. Mr.

Valle clarified that HPD has been collecting data since 2022, producing five public reports with de-identified data, including an analysis of prescription drug costs. He mentioned that data release for external researchers began in December 2024, allowing broader use of the information.

Dr. Ventura asked about the data enclave environment, questioning whether approved users would only analyze data within the system or if data could be downloaded. Mr. Valle explained that the HPD secure data enclave, referred to in statute as the secure research environment, provisions data on HCAI servers, allowing remote access but limiting direct transmission outside the environment. Each project has a separate virtual desktop, preloaded with statistical software, and all activity is logged and monitored. No data can be removed until fully de-identified and reviewed by HCAI staff. Upon project completion, access can be revoked, and the virtual environment is destroyed.

Dr. Schaeuble asked about cases where direct data transmission occurs. Mr. James Yi explained that regulatory policies outline requirements for direct access, while also noting that HPD is seeking common rule approval with a request for waiver of informed consent. He emphasized that HPD was developed through a public process, involving multiple stakeholder meetings focused on privacy, confidentiality, and security.

Mr. Yi pointed to a common rule provision that allows informed consent waivers for public benefit and service programs and requested CPHS to apply this provision to HPD.

Ms. Lund questioned whether HPD data would be strictly limited to research or if it could be used for other purposes. Mr. Yi confirmed that the Legislature intended HPD data to support broader healthcare innovations, beyond research, including limited non-research applications. Mr. Jared Goldman added that HPD is required to both receive and disclose information from payers.

Mr. Yi clarified that HIPAA does not govern HPD data collection, as California law mandates that insurers must provide the data. He emphasized that HPD has already received Medicare claims data from the Centers for Medicare & Medicaid Services (CMS), which was released under HIPAA's research provisions, aligning with common rule exemptions. He noted that CMS funded HPD, recognizing its benefit to Medi-Cal, Medicare, and Covered California. HPD has collected data on 33 million California residents, with 22 million receiving public health services, aiming to provide policymakers with a comprehensive view of healthcare trends.

Mr. Yi mentioned that obtaining informed consent for over 30 million people would be impractical, similar to CMS's reasoning for Medicare data. He referenced statutory language, which directs HPD to collect data on all California residents unless legally restricted. Allowing individuals to opt out could compromise database integrity, particularly for disadvantaged populations, some of whom may distrust government entities.

Dr. Azizian inquired about dental claims in HPD, and Mr. Valle explained that dental data collection is just beginning and that certain exemptions apply, including self-insured entities overseen by federal law and small health plans. Mr. Valle confirmed HPD captures over 90% of California's insured population.

Mr. Valle described HPD's data collection variables, which follow national data standards, including diagnosis, payment details, provider charges, out-of-pocket costs, and consumer enrollment data. Dr. Schaeuble asked whether any information is excluded, and Mr. Valle stated that data release conditions ensure only the necessary data for research is provided.

For further clarification, Mr. Wade Iuele explained that HPD follows the common data layout of California's All Payer Claims Database (APCD), which contains less information than raw claim file formats but is structured for efficient research analysis. Dr. Dickey then asked about how other states manage APCDs, acknowledging that California is not alone in implementing such databases.

Mr. Valle confirmed that over 20 states have similar databases. He mentioned an upcoming national meeting in Texas to discuss APCD administration and the National Association of

Health Data Organizations, which governs data standards for these databases.
Dr. Schaeuble sought clarification on what information is excluded from HPD. Mr. Chris Craig explained that HPD uses the common data layout (CDL), which includes disease codes, demographics, addresses, and payment details but excludes certain paperwork elements and physician comments. He noted that the CDL provides a comprehensive view for research and policy analysis.
Mr. Yi reiterated that obtaining informed consent for millions of individuals is impractical and that HPD aims to collect complete data for policymaking. He outlined privacy protections in HPD, including the secure research enclave, Article 8 of the Information Practices Act, and restrictions on individual data access. HPD cannot be used for individual decisions or healthcare payments and has strict data release criteria. HPD differentiates limited data sets from research-identifiable data, imposing higher security standards for identifiable data. Mr. Yi detailed the regulatory process for external data requests, explaining that HPD requires users to justify why they need direct data transmission instead of using the secure enclave. He described checks and balances, including reviews by the HPD Data Release Committee, CPHS, and the California Department of Health Care Services (DHCS) for sensitive research requests.
Ms. Lund asked who determines sensitive data requests, and Mr. Yi clarified that statute mandates CPHS review research-identifiable data and custom limited data sets. He explained data use agreements required by HPD and noted violations would be subject to civil code penalties.
Mr. Yi explained the privacy and security assessments, including reviews by the California Military Department, the California Department of Technology (CDT), and CMS, which evaluates HPD security before granting Medicare data access. Mr. Yi emphasized CPHS's role in HPD data releases, and Mr. Valle expressed HCAI's commitment to working with CPHS on processing research-identifiable data.
Dr. Dickey reiterated that the committee is reviewing the HPD database itself, rather than individual data requests, which will be addressed later. He identified policies and procedures as a key issue and noted that the committee had received a data management plan and a data use agreement with CMS. He confirmed that data use agreements will be required for entities accessing HPD and Mr. Yi mentioned that no agreements have been executed yet, though a template with DHCS is in progress.
Dr. Dickey asked if the California Military Department referred to the National Guard and if the California Department of Technology (CDT) would continue reviewing the system. Mr. Craig confirmed CDT’s ongoing audits, explaining that HPD follows NIST (National Institute of Standards and Technology) Special Publication 800-53, which includes over 1,000 auditable security controls. He described independent security assessments, including risk evaluations, penetration testing, and biannual security reviews. CMS requires these tests as part of federal funding compliance.
Ms. Kurtural asked whether HPD was developed in-house or through contractors. Mr. Valle explained that HPD was designed as a modular system based on stakeholder recommendations, avoiding reliance on a single vendor. HPD has a platform vendor responsible for collecting commercial claims data, while some components, like the master person index, remain within HCAI’s local environment.
Ms. Kurtural confirmed that HCAI is the primary administrator and asked whether any outside agencies had comparable control over HPD. Mr. Valle clarified that a technology partner assists with data collection and the research data enclave. Mr. Craig emphasized that all HPD vendors are bound by strict security agreements beyond standard IT provisions. He highlighted weekly security meetings with technology partners and emphasized on tight security integrations across teams. He described HPD as one of the most secure platforms he has worked on in statewide health IT.
Ms. Lund asked whether HPD data would be shared with other states, and Mr. Yi responded

that while no such requests have been made, the possibility has not been formally addressed. Ms. Lund expressed concerns about data misuse, particularly regarding women's reproductive health history. Mr. Yi reassured that regulations govern external data requests, and applications are closely evaluated to ensure that data releases do not pose risks to individuals' health or safety.

Mr. Jared Goldman emphasized that identifiable information requests would be carefully reviewed and denied when appropriate. Ms. Lund requested further clarification about the oversight of data releases, noting that the committee's review of HPD falls under the Common Rule, while subsequent research studies would be subject to IPA regulations.

Mr. Craig acknowledged the sensitivity of reproductive health data, explaining that California laws prohibit sharing such information with other states. He emphasized that data release reviews prioritize protections against potential harm. Ms. Lund raised concerns about other data fields, including gender identity, transition surgeries, and country of birth, suggesting that even non-statutorily protected data could be risky.

Dr. Azizian asked whether mental health data is included in HPD. Mr. Valle confirmed that insured claims related to mental health are captured, though many mental health expenses are paid out-of-pocket and thus not recorded in HPD.

Dr. Schaeuble noted that understanding HPD's secure data enclave and its broader use is crucial since the database has value only when utilized. Dr. Dickey agreed, stating that HPD's function must be evaluated not just as a database but also in terms of its applications and implications.

Dr. Schaeuble raised concerns about the vulnerable populations, suggesting it should explicitly acknowledge that Medi-Cal data includes vulnerable groups. He also questioned the description of risks, noting that sensitive claims—such as mental health and gender-affirming care—are included, raising privacy concerns if the database were ever compromised.

Dr. Schaeuble asked clarification on CPHS review requirements, questioning whether CPHS has discretion in reviewing data release requests or if its role is strictly dictated by statute. He suspected that many research projects may proceed with de-identified data, bypassing CPHS review, and asked whether this would be the majority of cases. He also referenced research on de-identified data, mentioning that re-identification risks are more significant than commonly assumed.

Mr. Valle explained that HPD follows Health and Human Services Agency's de-identification policy, which is currently under revision. Mr. Yi clarified statutory distinctions between limited datasets and research-identifiable data, as well as enclave access versus direct transmission, noting that CPHS review is required for research-identifiable data but not for standard limited datasets.

Ms. Kurtural asked about HPD's de-identification methodology, and Mr. Yi confirmed that only aggregated and de-identified public data products can be released under HPD statute. HPD follows agency de-identification guidelines, ensuring that data is officially de-identified before release.

Dr. Schaeuble inquired clarification on whether limited datasets released to researchers qualify as "publicly available data", and Mr. Yi confirmed that they do not, as such releases are governed by strict regulations. Dr. Schaeuble then described a possible situation where a researcher attempts to link HPD data with external sources using probabilistic matching. Mr. Yi acknowledged that this could happen but stated that HPD requires researchers to disclose their data-linking intentions in their applications. The HPD Data Release Committee has statutory discretion to review such cases, even if they would not normally fall under their purview.

Dr. Schaeuble asked whether HPD could refer such cases to CPHS, and Mr. Yi responded that nothing prevents it, but CPHS's authority over limited dataset requests is advisory rather than controlling. CPHS could provide recommendations, but statute does not grant it decision-making power in those cases.

Mr. Valle acknowledged Dr. Schaeuble's concerns about data linkage, emphasizing that similar issues have been raised in HPD Data Release Committee meetings. Dr. Dickey asked whether data use agreements (DUAs) would explicitly regulate data linkage, and Mr. Yi responded that DUAs could vary case-by-case based on specific use and data type.
Dr. Schaeuble then asked whether safe harbor data could still be re-identified, given the database's size and scope. Mr. Yi acknowledged that this is a challenging issue, explaining that HPD relies on existing de-identification standards, which apply to all agency-reported public data. Mr. Valle added that a group is currently evaluating these standards to determine if changes are needed.
Dr. Rykaczewska CPHS Administrator requested clarification on data access within virtual machines, concluding that researchers only access approved datasets rather than the entire database. Dr. Hess asked whether most data linkages would occur within the enclave, and Mr. Yi responded that this is the intended approach. Mr. Valle noted that the Data Release Committee, composed of healthcare and data security experts, plays a role in oversight and setting standards for researchers.
Dr. Dickey mentioned that informed consent waiver criteria require that the project be state-conducted and serve public health purposes. He noted that informed consent cannot be waived for individuals who were given the option to provide broad consent and declined. Mr. Yi confirmed that HPD data was not collected with broad consent.
Mr. Jared Goldman explained that the HPD statute does not require informed consent or allow opt-outs, as such provisions would undermine the database's purpose. The statutory language implicitly prohibits opt-outs and consent requirements.
Dr. Azizian asked whether physician notes are collected in HPD. It was confirmed that only claims and encounter data are included, excluding medical charts or images. Mr. Craig added that while electronic health record (EHR) systems contain detailed information, HPD primarily focuses on payments and services rather than clinical documentation.
Mr. Valle explained that since 2018, HPD has spent a one-time $60 million appropriation and is requesting $22 million for continued operation. He mentioned Covered California's use of HPD hospitalization data, which saved $20 million in one year by refining risk calculations for managed care costs. Also, HCAI developed its own workflow for data requests, offering to share it with the committee.
Dr. Schaeuble asked about specific findings that contributed to cost savings, and Mr. Valle explained that lower emergency department visits, fewer readmissions, and an overall healthier population mix were key factors. He offered to provide a detailed report on these findings.
Dr. Dickey acknowledged that the complexity of the discussion might be overwhelming for members, confirming that the issue of informed consent had been resolved. He proposed postponing approval of the HPD project to allow more time for operational concerns to be addressed.
Mr. Valle expressed respect for the committee's reviews and willingness to share further information. He noted that since December, HPD has received 12 data requests, indicating strong interest from the research community. Dr. Hess proposed that committee members submit further questions through CPHS Administrator, Dr. Rykaczewska, who would forward them to the appropriate HCAI representatives to streamline communication.

Public comments were invited, but no members of the public provided input.

Motion: Dr. Dickey moved, and Ms. Lund seconded, to table the discussion and revisit it at the June meeting. Committee members should submit any questions to the Administrator for forwarding to the HCAI team.

Approve: Dr. Dickey, Ms. Lund, Dr. Azizian, Dr. Johnson, Ms. Kurtural, Dr. Palacio, Dr.

Schaeuble, Dr. Ventura.
Oppose: None.
Abstain: None.
Absent: Dr. Dinis, Dr. Ruiz.

G. Full Board Continuing Review

None.

H. Amendments – Full Committee Review Required

1. Project # 2023-123 (Dickey)
Title: Risk Stratified Survivorship Care Pathways for Early-Onset Colorectal Cancer (the Survive-CRC Study)
PI: Ann Hamilton, PhD
Keck School of Medicine
Los Angeles, CA

Discussion:

Dr. Dickey explained that the amendment added another arm, another intervention, and another survey. While there were no major concerns, it was decided that such amendments should be shared with the committee rather than being approved individually.
The co-principal investigator explained that the project was funded through an R37 grant from the National Cancer Institute (NCI) and focused on understanding surveillance and survivorship care needs for patients diagnosed with early-onset colorectal cancer, specifically those younger than 50 years of age. The research involved partnerships with three Surveillance, Epidemiology, and End Results (SEER) cancer registry sites, including the Los Angeles registry. The study utilized SEER cancer registry data to assess the risk of recurrence and surveyed 3,000 patients to gather information on their care needs across different domains. The goal was to use this data to develop recommendations for risk-stratified survivorship care pathways. The amendment proposed adding a survey for the primary care supporters of patients to better understand their needs and ensure the recommendations applied to both patients and their supporters. Previous literature in other cancer studies suggested that care supporters have significant supportive care needs, but little was known about the care needs of younger patients with colorectal cancer and their supporters.
It was explained that care supporters would be identified through patient surveys, where patients would indicate whether they had a primary care supporter and their relationship with that person. The study planned to sample a total of 800 care supporters across all sites, with 300 specifically from Los Angeles. Since researchers did not have direct contact information for the care supporters, the surveys would either be passed along by the patients or mailed directly if the supporter lived separately. This method had been used in previous studies involving care supporters of older cancer patients and was considered effective.
Regarding informed consent, the research team expected no issues and planned to request a waiver of informed consent, treating the completion of the survey as consent. Additionally, the second aim of the amendment involved interviewing fifteen care supporters and fifteen patients to explore barriers to accessing survivorship and supportive care services. Verbal consent would be obtained for these interviews at the time they were conducted.
The committee inquired about the interview script, and it was noted that it had not been provided. Dr. Dickey stated that the interview portion could not be approved until the script was submitted, and the research team confirmed that draft interview scripts were available.

The research team explained that the survey focused on access to supportive care services and identifying unmet needs across several domains, similar to the patient survey, which had already been approved. Some questions addressed mental health, but participants were clearly informed that they were not required to answer any questions they felt uncomfortable with, as participation was entirely voluntary.
The primary reviewer stated that the survey itself seemed acceptable, and no other concerns were raised except for the need to review the interview scripts. There were no public comments made in person, and the discussion concluded.

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

—Please submit the interview guide and the consent script for the interviews.

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

2. Project # 2023-190 (Lund)
Title: Digital Self-Management and Peer Mentoring Intervention to Improve the Transition from Pediatric to Adult Health Care for Childhood Cancer Survivors
PI: Katie Devine, PhD
University of Southern California
Los Angeles, CA

Discussion:
Ms. Lund introduced Amendment 2023-190, explaining that it was brought to the full board due to significant changes involving direct participant interactions, questionnaires, consent forms, and recruitment materials. She had reviewed the amendment and asked Dr. Miller to describe the modifications.
Dr. Miller explained that the study is a National Cancer Institute-funded randomized controlled intervention aimed at improving self-management of survivorship care among 300 young adult survivors of childhood cancer. The study is conducted at Rutgers Cancer Institute of New Jersey, using recruitment through the New Jersey State Cancer Registry, and at University of Southern California (USC) in Los Angeles, recruiting through the Los Angeles Cancer Surveillance Program and the California Cancer Registry. She clarified that the amendment includes personnel updates, additions to participant surveys, revisions to the eligibility screener, informed consent modifications to align with USC's standards, updates to participant-facing materials like the recruitment flyer, and the introduction of a participant website.
Ms. Lund pointed out that several additional questions had been added to the participant surveys and initially seemed unrelated to the study’s goals. She specifically mentioned cannabis use, mammography, and ECG screenings. Dr. Miller clarified that these questions are from the intervention itself, which aims to encourage survivors to engage in cancer-focused survivorship care, including counseling on preventive screenings and lifestyle behaviors. One module in the intervention addresses substance use and healthy lifestyle choices, making the newly added questions relevant to measuring its impact.
Ms. Lund then asked about the reason for the removal of bullet points at the beginning of the

consent form, noting that OHRP guidance suggests providing a summary at the start to help participants quickly understand what to expect. Dr. Miller explained that the changes were made to harmonize the consent form with USC's standard format but confirmed that the bullet points could be restored. Ms. Lund emphasized that reinstating them would improve readability, and Dr. Miller agreed.
Concerns were raised about the consent form's readability, with Ms. Lund noting it appeared to be at a higher reading level. Dr. Miller confirmed that the Flesch test rated it at a 10th-grade reading level, mostly because of the necessary details regarding randomization in the study design.
Dr. Schaeuble requested that key phrases in the "Future Use of Data and/or Specimens" section on page 5 of the consent form be emphasized in bold, underlined, or capitalized for clarity. These included:
• "…without obtaining additional informed consent from you."
• "We plan to keep your data and/or biospecimens indefinitely."
• "If you are not comfortable with this, you should not participate in this study."

Dr. Miller agreed to highlight these phrases and requested formal notes to ensure accuracy.

Dr. Dickey questioned whether USC IRB could potentially reject the request to reinstate bullet points and suggested framing the request as a recommendation rather than a requirement.

Dr. Miller clarified that USC had ceded IRB oversight to CPHS for the study, meaning CPHS would have the last word on it.
No public comments were made regarding the amendment.]
Motion: It was moved by Ms. Lund and seconded by Dr. Dickey to grant a deferred approval, minimal risk pending the following specified minor revisions which require expedited review and approval by a CPHS subcommittee of Ms. Lund.
1. Restoration of the bullet points at the beginning of the consent forms.
2. Emphasize the following three phrases on page 5 of the consent form:
   • "…without obtaining additional informed consent from you."
   • "We plan to keep your data and/or biospecimens indefinitely."
   • "If you are not comfortable with this, you should not participate in this study."

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

I. Second Review Calendar

None.

J. New Projects – Expedited Review Requested

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

K. 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)

L1. 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 (101)

L. Amendments – Projects with Revisions Approves through Expedited Review

Some projects listed may have been approved by expedited review prior to this meeting and were not reviewed by the full committee.
Total Project Count (22)

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

None.

N. Exemption/Not Research Approvals

Total Project Count (16)

O. Final Reports

Total Project Count (9)

P. Public Comments

None.

Q. Next Meeting

The next CPHS meeting is scheduled to be held on Friday, June 6, 2025.

R. Adjournment

This meeting was adjourned at 12:32 PM on April 25, 2025.