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

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

GAVIN NEWSOM
Governor

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

Members
Catherine Hess, PhD, M.Phil. (Chair)
Larry Dickey, MD, MPH, MSW (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
Allen Azizian, PhD
Alicia Bazzano, MD, PhD
Maria Dinis, PhD, MSW
Juan Ruiz, MD, DrPH, MPH

Alternate Member
Millard Murphy, JD
Lois Lowe, PhD

Friday, March 7, 2025
8:30 a.m.

Zoom:
CPHS March 7, 2025, Full Committee Meeting

Meeting ID: 161 920 7384
Passcode: 869116

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

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Meeting ID: 161 920 7384

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, MSW
Carrie Kurtural, JD
Maria Ventura, PhD
Jonni Johnson, PhD
Laura Lund, MA

Committee Members Present Remotely:

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

CPHS Staff Present in Person:

Agnieszka Rykaczewska, PhD
Sussan Atifeh
Karima Muhammad
Nicholas Zadrozna

Also, Present (All via ZoomGov) Principal Investigators and Associate Investigators

Stephen Henry
Ben Mooso
Erika Bustamante
Evan White
Judy Rees
Kay Chang
Angelique Lastinger
Regan Foust
Sibylla Leon Guerrero
Ben Obrien
Michael Hoyt
Emily Dang
Jennifer Tsui
Jessica Schleider
Gina Misch
Andy Rapoport

A. Welcome

a) Swearing in Ceremony

Dr. Agnieszka Rykaczewska, CPHS Administrator, swears in Dr. Catherine Hess as the Committee for the Protection of Human Subjects (CPHS) Chair next to the American Flag in front of the other committee members.

b) Chair Updates

Dr. Hess informs the committee that changes are happening to the policies and procedures but is going to adhere to the current policies and procedures until any changes are made formally to the Polices and Procedures. The formal process of changing the policies and procedures requires the secretary to sign off on the changes being requested by the committee.

Ms. Lund asked if the changes to the policies and procedures will include the updated flow chart for Common Rule and IPA reviews that Dr. Rykaczewska presented with legal counsel during the committee in the November 1, 2024, CPHS meeting. Dr. Rykaczewska let Ms. Lund the flow chart and the updates to the Policies and Procedures are still being finalized while the committee is under discussion regarding the proposed regulations to the IPA review.

Dr. Rykaczewska reminds the committee that all changes will be presented to the board for approval, before presenting it to the California Health and Human Services (CalHHS) Secretary.

B. Administrator Update

a) FDA Audit Update

Dr. Rykaczewska informed the committee that a routine audit by the FDA was completed. Only one observation was made during the audit, that the historical rosters were not properly maintained over the past five years. This will be addressed by documenting the CPHS administrative procedures when any changes to the board's roster occurs. Any changes to the boards roster would include when a member joins or departs from the committee. Past of the documentation will include instructions on how to properly store the historical roster and update the roster to ensure CPHS is maintaining those records appropriately.

b) Determine April Meeting Date

Since the committee would not have quorum for the April 4, 2025, meeting, it was proposed to change the date to another date in April. Dr. Dinis proposed April 25th, 2025, since April 18th is a Friday before Easter weekend.

No public comments were made in person or remotely.

Motion: Dr. Dickey moved, and Ms. Kurtural seconded moving that the next time CPHS meets is April 25th, 2025.

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

Total= 8 In favor- 8 Oppose- 0 Abstain- 0

C. Subcommittee Updates

Dr. Hess informed the committee that the Governor's office has requested that the committee defer consideration of the proposed IPA regulations until the April meeting.

D. Training Policy

Dr. Hess proposes that the Policies and Procedures are updated to require all new members to complete the CITI training within the first six months of their tenure on the board.
Ms. Lund asked if existing committee members have the same requirement. Dr. Hess strongly encourages that existing members take advantage of the CITI training, but the requirements have not been discussed yet for existing members, but strongly encourages that existing members take advantage of the trainings.
Ms. Lund informs the members that she has completed her CITI trainings and found the IRB protocol review training be the most useful. Ms. Lund expressed that the trainings provide information that is often discussed during the committee meetings and urges all the other members to do the same to be on the same page. Noting a lot of the discussions would not occur if all the members were on the same page with the requirements are and what should be considered during the review process. Ms. Lund expressed the importance of this committee, and that people's lives are in our hands from researchers to the people's data the committee overseas. Ms. Lund informed the committee that the information and security training was not relevant to this committee since the training is what you would provide to a new employee such as not leaving your screen open with private data. Ms. Lund expressed that the IRB Members training is extremely useful and encourages all members to take that training.
Dr. Dickey suggested to have the training completed in the first 6 months for new members and give existing members one year to complete the training. After the training is completed, a certificate is generated that last three years. Dr. Hess suggested not requiring members to take the training every three years, but to retake the training if any major updates occur or as needed.
Dr. Hess opened the discussion up to the Public.
Stephen Henry, a physician researcher, provided public comment viz zoom. Mr. Henry reiterated the comment by the committee that people's lives are in their hands is very apt and researchers who apply to this committee are required to spend dozens of hours a year on these trainings. Ms. Henry believes it is a important responsibility for anyone who chooses to volunteer for CPHS that they maintain regular review and certifications of these trainings. This would ensure everyone is on the same page and time is not wasted on committees arguing about things due to the differences in knowledge about established federal and state rules and practices.
No other public comments were provided to the committee.

Motion: It was moved by Ms. Lund and seconded by Dr. Dickey that CPHS Policies and Procedures be changed that new Committee Members complete the CITI trainings within 6 months from their appointment to the board, that existing Committee Members take the training within the 12 months from March 7, 2025, and that the Committee decides in the future when refreshers are necessary.

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

Total= 8 In favor-8, Oppose-0, Abstain-0

E. Review and Approval of Meeting Minutes

a) October 4, 2024, Meeting Minutes
No feedback was provided from the committee and no public comments were provided for the October 4, 2024, meeting minutes.

Motion: Dr. Ventura moved, and Dr. Dickey seconded the approval of the October 4th, 2024, meeting minutes.

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

Total= 7 In favor-7, Oppose-0, Abstain-1

Dr. Palacio abstained due to not present for the October 4th, 2024, meeting.

b) November 1, 2024, Meeting Minutes
No feedback was provided from the committee and no public comments were provided for the November 1, 2024, meeting minutes.

Motion: Ms. Kurtural moved, and Dr. Ventura seconded the approval of the November 1st, 2024, meeting minutes.

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

Total= 8 In favor- 8 Oppose- 0 Abstain- 0

c) December 6, 2024, Meeting Minutes
No feedback was provided from the committee and no public comments were provided for the December 6th, 2024, meeting minutes.

Motion: Dr. Ventura moved, and Dr. Johnson seconded the approval of the December 6th, 2024, meeting minutes.

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

Total= 8 In favor- 8 Oppose- 0 Abstain- 0

F. Projects with Reported Adverse Events and/or Deviations
None.

G. New Projects – Full committee Review Required

1. Project # 2025-011 (Ventura)
Title: Implementation of Soluna Single-Session Components in California Schools
PI: Jessica Schleider, PhD
Board Decision: Approved Pending Conditions - Designee Review

Discussion:
Dr. Jessica Schleider, an associate professor of Medical Social Sciences, Pediatrics, and Psychology at Northwestern University, is leading this project in collaboration with Kooth, a digital mental health company. Kooth has a contract with the state to deploy their app, Soluna, across California. The study aims to evaluate the accessibility, impacts, and added value of Soluna's single-session coaching op6tion, which is one of several different digital mental health tools available on the app. The focus is on single session interventions, which are designed to make the most impact in just one encounter, and Soluna is one of the few digital mental health apps that include these components. The research team will measure young people's use of the Soluna app, their emotions, thoughts, and well-being as well as their demographics. The study will recruit young people, ages 14 to 17, across California. These young people already have access to Soluna through the state's investment. They must have English proficiency, access to the internet, and pass a capacity-to-consent assessment. Participants will complete a baseline survey, a one-month follow-up, and a three-month follow-up and will receive up to $30 gift cards for their participation. The study will collect data through voluntary surveys conducted via Qualtrics, where participants will receive survey links through the Soluna app, which they already use. The research team hypothesizes that youth with access to Soluna will show reductions in stress, depression, anxiety, hopelessness, mental illness stigma, and loneliness, as well as increases in perceived social support and quality of life. They predict that more engagement with Soluna on more occasions will lead to larger improvements in these outcomes.

Additionally, the study will include a separate and complementary secondary analysis of 3500 to 4500 newly registered Soluna users during the project period. These users have already affirmed that their anonymous data can be used for research purposes. This secondary data analysis will help the team understand user engagement trends, uptake, and acceptability. The data is not medical data from DHCS, but the state owns the data through a contract with DHCS, and the team has already received approval from DHCS for data usage. All recruitment will happen within Soluna's platform, where students will receive a message about the study and if interested, will be directed to a Qualtrics web page to determine eligibility. Eligible participants will complete the baseline survey, followed by one-and three-month follow-ups. Each completed survey earns them a $10 gift card, up to $30 total. The study is minimal risk, but participants may feel discomfort dur to the survey length or content. However, they can skip any questions they do not want to answer. The study will also ask about suicidal ideation in certain surveys, and the research team, which specializes in adolescent risk assessment, has detailed rusk protocols in place. The study has already been approved by the Northwestern University IRB and follows standard data protections. The findings will help understand how Soluna is benefiting California young people, and the privacy protections are clearly outlined in the protocol submitted. The study will not impact Soluna's availability for anyone who already has access.
Dr. Ventura mentioned that the biggest concern was the waiver for parental consent since the study involves minors aged 14 to 17 and includes sensitive questions about suicidal ideation, sexual orientation, and gender identity.

Dr. Schleider responded by saying that their lab prioritizes waiving parental consent for their digital mental health research with adolescents because requiring it could exclude youth who may not be able to disclose mental health concerns to their families.

Ms. Lund pointed out that parents do not give consent, only permission , and that it is important to consider whether requiring parental permission would disadvantage the group being studied by making it harder for them to participate. It was clarified that youth already access Soluna without parental permission, so adding this requirement could limit participation.

Ms. Kurtural asked about how minores initially access the app and whether there is a screening process to determine if they are mature enough, as required by California law for minors under 18.

Dr. Schleider mentioned that Soluna is not a mental health service or treatment but rather a support tool open to all youth. It was clarified that there are onboarding questions to check whether users understand what Soluna provides and does not provide , including that it is not a replacement for therapy.

To clarify more details about the screening process and how the study determines a participant's capacity to consent, Dr. Schleider shared the inclusion criteria, which require participants to be 14 to 17 years old, proficient in English, living in California, have internet access, and pass a capacity-to-consent assessment.

Dr. Hess pointed out that since participants are minores, they can only assent, not consent, and suggested changing the language in the form and simplifying the explanation of how data will be used so that youth fully understand the study.

It was suggested by committee that researchers clearly state the total time required for all three surveys so that participants know their full commitment before agreeing to join.

To address concerns about risk assessment, particularly if a participant is found to be at risk of suicide or self-harm, Dr. Schleider explained that Soluna has its own risk response team and if researchers cannot reach a parent, they would contact Soluna for support.

The committee questioned how researchers verify that the parental contact information provided by youth is real and what would happen if the contact information was incorrect or unresponsive. Dr. Schleider admitted that they cannot guarantee 100% accuracy of the contact information but emphasized that this is a common limitation in online studies, and their approach is designed to be as inclusive as possible while maintaining safety measures.

Ms. Kurtural requested more information about the screening process, the app's contact with the state, and how risk situations would be handled.

Ms. Gina Misch from Kooth explained that Soluna is part of the Children and Youth Behavioral Health Initiative (CYBHI), a statewide program under Governor Newsom, which started in 2023. Soluna launched in January 2024 and is fully funded by the state to provide free behavioral health support for young people aged 13 to 25. She described the registration process, where users provide their date of birth to confirm their age and zip code to ensure they live in California. After registering, they first gain access to content and tools (such as articles, breathing exercises, and interactive graphics) without any human interaction. If they are 13 or older, they can also access coaching services, which include chat-based, video, or tele

coaching sessions with certified peer specialists, not licensed therapists. There are also moderated peer forums where users can post responses, but everything is reviewed by a human before being made public.

Ms. Kurtural questioned if there was any screening for users with developmental or intellectual disabilities who may lack the capacity to use the app. Ms. Misch explained that per the contract with the state, Soluna must be available to all young people aged 13 to 25 and there is no screening based on developmental disabilities. She emphasized that the tools and content are subclinical, meaning they are not therapy and should be accessible to all users.
Regarding the risk assessment on suicidal ideation, it was clarified that if risk is identified through the study's surveys, their detailed risk protocol would be followed. However, within the Soluna app itself a separate safeguarding system is in place, which includes mandated reporting when necessary.

The committee also raised concerns about youth in foster care or wards of the court, noting that these minors may require special permissions to participate in research. The PI stated that the current study does not ask about foster care status, so those youth are not identified or excluded. It was suggested that the study should screen for this and exclude wards of court, since they may need court approval to participate. The PI agreed and said they just need the exact working for the exclusion criteria. The committee also discussed data protection, part6icularly the risk of identifying individuals based on gender identity or sexual orientation in a small study population of 250-500 participants suggesting using CalHHS Deidentification Guidelines which provide stricter rules on masking small numbers in published data.

The committee suggested simplifying the language of the assent form to a sixth-grade reading level to ensure minors fully understand how their data will be used. The committee also approved the quiz system, where participants must correctly answer multiple-choice questions to demonstrate they understand the consent process.

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

1. Change the consent form to be assent only.
2. In the assent form, include more explanation on how their data will be used and details about what is expected if they participate.
3. Lowering the reading level of the assent form as much as possible, with a target of 6th grade.
4. In the screening criteria, there will be exclusion criteria to exclude wards of the State or other agency – CPHS will follow-up the exact language.
5. Will revise the data masking to align with the CalHHS Data Deidentification Guidelines.

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

Total= 7 In favor- 7 Oppose- 0 Abstain- 0

H. Full Board Continuing Review
None.

I. Amendments – Full Committee Review Required

1. Project # 2020-112 (Dickey)
Title: A Biobehavioral Intervention for Latino/Hispanic Young Adults with Testicular Cancer
PI: Michael A Hoyt, PhD
Board Decision: Approved Pending Conditions - Designee Review

Discussion:
Dr. Dickey informed the committee that since this project involved creating an entirely new wing of research, he recommended that the amendment be reviewed by the Full Committee. Dr. Dickey asked Dr. Hoyt to first explain the initial project to the committee before addressing the requested changes.

Dr. Hoyt explained that the original project was a small pilot study testing a behavioral cancer survivorship intervention for Latino young adults who had experienced testicular cancer. This study built upon previous work that Dr. Hoyt had conducted with this population. The pilot study has been completed, and additional funding has been secured to extend the research. The amendment was submitted to expand upon the previous work and test the same intervention with Latino young men who have had cancer. The main change in the new study is broadening the scope from only testicular cancer to include other cancer types. Additionally, an attention-matched control arm will be introduced to support a larger pilot study.

Dr. Dickey asked Dr. Hoyt to describe the intervention itself. Dr. Hoyt explained that the intervention focuses on skill-building and self-regulation, particularly in helping participants pursue their goals after experiencing cancer. The program is brief, consisting of six sessions spread over two months, conducted one-on-one via Zoom.

Dr. Dickey then inquired about the recruitment and screening process. Dr. Hoyt explained that the recruitment strategy mirrors the approach used in the pilot study. Participants are identified through the California Cancer Registry, which provides a list of potentially eligible subjects. They are first contacted via a letter explaining the study and providing details on how to reach the research team. Follow-ups are conducted after a designated period, and additional recruitment efforts take place through clinics at UC Irvine. Flyers are also posted at various cancer care organizations to allow interested individuals to self-identify and reach out to the research team. Dr. Dickey emphasized the importance of transparency in participant outreach and requested that the initial contact letter explicitly inform recipients that their contact information was obtained from the California Cancer Registry. Dr. Hoyt agreed to incorporate this change. Ms. Lund suggested developing a contact script that clearly states whether participants' information was acquired from their physician or from the California Cancer Registry, ensuring that participants fully understand the sources of their data.

Dr. Dickey then asked about the script for the control group and what is discussed during their sessions. Dr. Hoyt explained that the sessions are participant-driven, meaning the discussions are based on whatever topics the participants bring up. Interventionists are trained in active listening and use reflective listening techniques but do not engage in structured exercises or work on coping skills or emotion regulation.

Motion: Dr. Dickey moves and Ms. Kurtural seconds for deferred approval of the amendment, Minimal risk with the changes in the recruitment letter to state that they've been recruited because they have been identified as having cancer either in the California Cancer Registry or through your provider with review by Dr. Dickey as a subcommittee.

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

Total= 8 In favor- 8 Oppose- 0 Abstain- 0

2. Project # 2023-117 (Lund)
Title: Assessing Cervical Cancer Healthcare Inequities in Diverse Populations: The ACHIEVE Study
PI: Jennifer Tsui, PhD, MPH
Co-PI: Lihua Liu, PhD, Adana Llanos, PHD, MPH, Chanita Hughes Halbert, PhD
Board Decision: Approved Pending Conditions - Designee Review
Discussion:
This amendment introduced significant changes to a previously approved research project. In the original study, researchers had planned a twelve-month follow-up survey but did not include the associated consent forms, questionnaires, and recruitment materials. The amendment formally added these elements to the study.
Dr. Jennifer Tsui, associate professor at the University of Southern California (USC), presented the amendment, noting that the study recruits cervical cancer patients from the New Jersey State Cancer Registry and the Los Angeles Cancer Surveillance Program (LACSP).
The amendment introduced three main changes:
1. The twelve-month follow-up survey and its associated recruitment materials were added. In this twelve-month follow up survey, Some baseline survey items were removed while new ones were introduced.
2. minor updates were made and approved to the English version of the baseline survey, through the amendment submitted for this project on December 23, 2024, and this amendment included the finalized Chinese and Spanish translations of those updates
3. The process for requesting medical records from physicians was expanded. Initially, only registry staff were responsible for this task, but the amendment included trained research staff in this role to improve efficiency.
Ms. Lund confirmed that the updated consent form language addressed her concerns and found the follow-up questionnaire appropriate.
No public comments were received regarding the amendment.

Motion: Ms. Lund moved, and Dr. Ventura seconded, to approve the amendment.
Approve: Ms. Lund, Dr. Ventura, Dr. Dickey, Dr. Dinis, Dr. Johnson, Ms. Kurtural, Dr. Palacio, Dr. Ruiz.
Oppose: None.
Abstain: None.
Absent: Dr. Azizian, Dr. Schaeuble.

Total= 8 In favor- 8 Oppose- 0 Abstain- 0

J. Seconder Review Calendar
None.

K. 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 (20)

L. 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 (105)

L1. 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 (30)

M. 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 (39)

N. Projects with Requests for CPHS to Rely on Another IRB
None.

O. Exemptions/ Not Research Approvals
Total Project Count (14)

P. Final Reports
Total Project Count (4)

Q. Public Comments
Dr. Hess opened the discussion up for public comment.

Ms. Lund asked that the committee allocate time in a future meeting to hold a joint discussion on IPA reviews. She expressed concerns about the handling of data sets that contain personally identifiable information (PII), particularly considering potential legal risks under the current administration and in certain states. Specifically, she highlighted the possibility that medical record information; including details related to reproductive health care, immigration status, and status of non-binary or transgender individual could be criminalized under the current administration.
Ms. Lund raised concerns about the committee's role in approving research that allows out-of-state researchers access to these sensitive data sets, especially when the states are now passing laws that criminalize some of these behaviors that can be discovered in these data sets. Ms. Lund suggested exploring measures to safeguard participants' information, such as requiring certificates of confidentiality for data sets that are sent out of state. Additionally, she questioned whether CPHS should seek assurances from the universities housing the data that they will not release record-level data if CPHS allows them to hold it.
No additional public comments were provided. Dr. Hess acknowledged that CPHS has received 14 public comments that have been posted to the website.

R. Next Meeting
The next CPHS meeting is scheduled to be held on Friday, April 25th, 2025.

S. Adjournment
This meeting was adjourned at 11:13 P.M on March 7th, 2025.