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, December 6, 2024
8:30 a.m.

Zoom:
CPHS December 6, 2024, Full Committee Meeting

Meeting ID: 160 333 6696
Passcode: 923597

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

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Meeting ID: 160 333 6696

MINUTES

Members
Darci Delgado, PsyD. (Interim Chair)
Larry Dickey, MD, MPH, Vice Chair
Juan Ruiz, MD, DrPH, MPH
Alicia Bazzano, MD, PhD
Maria Dinis, PhD, MSW
Catherine Hess, PhD
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
Alicia Bazzano, MD, PhD
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

Committee Members Present in Person:

Darci Delgado, PsyD
Larry Dickey, MD, MPH
John Schaeuble, PhD, MS
Maria Ventura, PhD
Jonni Johnson, PhD
Carrie Kurtural, JD
Catherine Hess, PhD
Laura Lund, MA

Committee Members Present Remotely:

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

CPHS Staff Present in Person:

Agnieszka Rykaczewska, PhD
Sussan Atifeh
Karima Muhammad
Nicholas Zadrozna

Center for Data Insights and Innovation Staff Present in Person:

John Ohanian, Director
Agnieszka Rykaczewska, Deputy Director

California Health and Human Services Staff Present Remotely:

Jared Goldman, General Council
Maggie Schuster, Attorney

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

Chanita Hughes Halbert
Tristan Beard
Lihua Liu
Evan Graboyes
Matthew Cooperberg
Scarlett Lin Gomez
Laura Allen
Anshu Shrestha
Sophie Zhang
Claire Conley
Agnes Balla

A. Welcome

a) Chair Updates

Dr. Delgado calls to order the December 6, 2024, CPHS meeting, reminding the committee members that are attending remotely via zoom to keep their camera's on during the meeting. Sussan Atifeh calls roll call to establish quorum. Dr. Delgado informs the committee that Dr.

Bazzano has submitted her resignation from Committee for the protection of Human Subjects (CPHS) since she has accepted a tentative offer to head Pediatric Ethics at the Food and Drug Administration (FDA). Dr. Bazzano noted how important the impact that CPHS does for individuals across the state and nationally. She mentioned that over 15 years being a part of CPHS has contributed to being able to work nationally and appreciated spending the time with everyone at CPHS.

Dr. Delgado emphasized Dr. Bazzano's ability to balance the protection of human subjects and meeting the needs of the researchers. Dr. Delgado thanked Dr. Bazzano for everything she's done for CPHS.

Dr. Dickey expressed gratitude towards and inquired about the ability to consult with Dr. Bazzano in the future. Dr. Bazzano noted that there is enough overlap with the FDA and CPHS that there can be a potential conflict of intertest.

Dr. Dinis expressed this will be a big loss for CPHS, but this was wonderful for Dr. Bazzano, and her service is much needed within the new federal administration.

Ms. Lund thanked Dr. Bazzano for her intelligence and thoughtful reviews during the years of service. Ms. Lund thanked Dr. Bazzano for all the knowledge she has learned so much from her.

B. Nomination of New CPHS Chair

a) Nomination of CPHS Chair by CDII Director John Ohanian

Director Ohanian thanked Dr. Delgado for stepping in as the interim Chair for the past year for CPHS and her leadership during this critical time. Director Ohanian formally nominated Dr. Katie Hess for the CPHS Chair position, and her bio and CV is included in the meeting materials.

Director Ohanian shared some key highlights from Dr. Hess's CV and bio. Dr. Hess received a Doctorate from Bournemouth University in Environmental Anthropology. Dr. Hess has an extensive background in epidemiological work, including Dr. Hess's work in investigating how residential segregation impacted exposure to toxic metal pollution in urban Apartheid South Africa.

Dr. Hess was a post-doc fellow at both John-Hopkins and UC Berkeley, leading critical research in tobacco, e-cigarettes, and alcohol use. Dr. Hess currently serves as the Chief of the Epidemiology and Evaluation Unit under the Substance and Prevention branch within the California Department of Public Health (CDPH). Dr. Hess is leading research focused on substance use including tobacco, cannabis, alcohol, and opioids.

Dr. Hess has a deep level of expertise and research ethics. She has been a committee member of CPHS since 2021. Director Ohanian expressed that Dr. Hess meets all the selection criteria within the CPHS Policies and Procedures. The criteria would include having employment within a department under California Health and Human Services (CalHHS) and being a part of CPHS for a minimum of two years.

Dr. Hess has expressed interest to Director Ohanian for stepping in as the CPHS Chair and CDPH has already endorsed her nomination. The committee must vote on whether they endorse Dr. Hess' nomination.

Dr. Delgado advised being the Chair exposed her to different aspects of the board such as administrative functions. The last year Dr. Delgado was Interim Chair it provided opportunity to expand her knowledge and recommends the other committee members to be open to taking the Chair position after Dr. Hess's tenure. Dr. Delgado recommended Dr. Hess as the Chair and thanked her for her interest.

Dr. Delgado opened the discussion up for public comment. No public comments were made at the time.

Motion: Ms. Lund moved, and Dr. Dickey seconded that CPHS accept the nomination of Dr. Hess as Chair of CPHS.

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

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

Director Ohanian advised that with the CPHS endorsement, CDII will submit the nomination to Secretary Johnson for appointment and will be sworn in during the next meeting in February 2025.

C. Subcommittee Updates

a) Review proposed text and questions from subcommittee meeting on November 8, 2024

Dr. Delgado asks Ms. Lund to provide updates from the November 8, 2024 CPHS Sub-Committee Meeting. Ms. Lund noted that the subcommittee meet to support the development of regulations to support IPA reviews on November 8, 2024. The subcommittee discussed and reviewed the evolved document originally prepared by Dr. Schaeuble.

The motion was shared on the screen. The recommendation form the last subcommittee meeting is to provide a supporting document that describes what is required in the Information Practices act (IPA) and describes the risks CPHS is concerned about for the projects that come under CPHS purview. The third section of Dr. Schaeuble's document addresses what CPHS would like to ask researchers when they submit their project for IPA review. This section of the document is what majority of the discussion revolved around and the language changes to the third section were made to minimize redundancy.

The subcommittee discussed different criterion that should be applied. During the meeting there were a lot of discussion, issues raised, and concerns within the subcommittee but no resolution was made. The subcommittee recommended bringing this to the full board committee for discussion and resolution today.

The three questions the subcommittee brought to the full board attention:

1. Restrict the request for Notice of Privacy Practices (NPP) documents and description of procedures to only studies that propose to link data from multiple data sources or
2. Do we want to include requests for NPP documents and description of procedure to all studies reviewed under the IPA? or
3. Do we want to have the NPP and description of procedures only for studies meeting one of the risk criteria enumerated in the document?

Ms. Lund opens the discussion to the committee members to gather feedback and questions.

Dr. Delgado asked a clarifying question, for this to be framed in the bigger picture of the regulations process. Ms. Lund advised once CPHS finalizes the supporting documentation and everything that the subcommittee is working on, the Center for Data Insights and Innovations (CDII) legal team will draft regulation language. Once the language is finalized it will go through the regulation process the regulations are posted for public comment. The public will have a window of time to submit public comments, and all the public comments must be reviewed either by being incorporated or addressed.
Dr. Agnieszka Rykaczewska added that once the regulation language is drafted up, it will be brought back to the full committee for endorsement before submission.

Ms. Kurtural advised her opinion for IPA reviews if the CPHS should request additional documentation should be more narrowed. Her concerns are with the higher risk projects that the researchers are taking the State of California data and merging it with outside source data. Ms. Kurtural notes it would be helpful for the applications that present scenarios with higher risk, that CPHS look at and request additional documentation with respect to the outside source data.

Ms. Kurtural provides the example, that the State of California has an Agency handle on the eligibility process which counties and regional centers go through for the Notice of Privacy Practices (NPP). CPHS reviewers would not have the information about the outside data sources connected to projects, nor would CPHS know anything related to the outside source data being connected to the state of California data. This is where additional information would be helpful.

Dr. Schaeuble advised that he has differencing opinions than Ms. Kurtural. Dr. Schaeuble suggest that using studies that involve linkage to other data as a threshold is not the best way for CPHS to go. He suggests that the outcomes are less than desirable with that approach. Noting some of the projects captured by this threshold are studies in which the linkage to other data does not cause a noticeable increase in risk. Some of the linkages to other data are to variables or to information that is not sensitive. Some studies raise the kinds of risk CPHS has listed in the middle of the supporting document, due to the variables researchers are working with, or the way in which researchers are working with the variables.

Dr. Schaeuble advised he is troubled by what researchers might try to do under these circumstances. Suggesting that researchers might choose to initially submit a project stating there is no linkage from state data to outside data because the review process would be less cumbersome. Then later, the same research study will come back to CPHS with an amendment to add linkage to the other data. Thus, CPHS' initial review will be done with incomplete information about the study, under a potentially misleading context in which to try and understand the study.

Dr. Schaeuble suggests that CPHS should want researchers to look carefully at the risks CPHS has identified as important and make their own determination on whether those risks apply to

their research, and if so, to provide the information about how that risk applies in their study and how they are handling it, to minimize the effects of it, and provide CPHS with the corresponding information in their application. If for some reason the researcher misses something CPHS feels they should address, CPHS has the option to go back to the researcher and ask them to consider possible risks and address how they will handle those risks.

Dr. Schaeuble suggests the third alternative is the best option since it focuses on the studies where some of the risks identified by CPHS are present in the study. CPHS would not limit themselves to the one situation of linkage data but take a global approach by asking if any of the risks exist, and if so, what is being done about the risks.

Dr. Dinis agreed with Dr. Schaeuble, advising the risks CPHS identifies need to be included. CPHS is aware that studies with data linkages are more concerning but there are other risks that come up and CPHS should be able to apply the regulations to those risks, whatever they may be. It's hard for CPHS to anticipate those risks with AI and other technological advances. Dr. Dinis suggests It's better for CPHS to be more inclusive than to exclusive.

Ms. Lund advised it's too restrictive for CPHS to only consider data linkages. CPHS enumerated all the risks in the supporting document because these are critical to CPHS. Returning to the language of the IPA, CPHS wants to ensure there are sufficient procedures in place for data, security, and confidentiality and that CPHS does their due diligence in those areas.

Ms. Lund advised it's too burdensome for researchers to go with the second option. If CPHS receives an IPA study that does not have one of the risks identified in this document, it is not necessary for CPHS to ask researchers to do additional work to provide the NPP and other supporting documentation.

Ms. Lund agrees with Dr. Schaeuble and Dr. Dinis that the third option is the best solution. That CPHS would want to ask for the additional documentation for the studies that have the risk factors that have been identified in the supporting document.

Ms. Lund suggests that for Dr. Schaeuble's concern that when researchers initially submit an application with no plans to do data linkage and come back later with an amendment that says they're going to do a linkage. Ms. Lund recommends applying the same standards to requests for amendments that are applied when an original protocol when it's submitted.

The discussion was opened to the full CPHS committee for thoughts, comments, and discussion as CPHS needs to resolve this issue to move forward. The CPHS sub-committee is requesting discussion and recommendations from the full committee. Once CPHS agrees upon the language, the document will be turned over to the legal team for development of the regulations. Once this outstanding work is complete, CPHS will have nothing else to do with the regulations as a board or a sub-committee until the legal team completes their first draft of the regulations.

Dr. Schaeuble advised the sub-committee is looking for the full committee to give a decision among the three alternatives so the sub-committee can make language revisions at their next meeting. It was agreed there needs to be a motion at the end of this discussion.

Dr. Hess advised the third option makes the most sense because the list of risks includes linked data. Dr. Hess agrees with Ms. Lund that requiring all this documentation for all projects is unfeasible for the researchers and CPHS.

Dr. Schaeuble suggest that researchers should self-identify whether their project involves any of the risks enumerated in the supporting document. A CPHS reviewer would only have to call out a project for additional questions if the researcher hasn't responded to something that CPHS thinks they should have responded to. In the supporting document, there is a lengthy list of potential risks that are concerning but not all risks will apply in most of the studies CPHS sees. Researchers should only be asked to respond to those risks that are involved in their studies.

Dr. Dickey advised the current language in the supporting document states that CPHS reviewer 'will' take the response into consideration. It does not say 'may' or 'can' judge the severity of it. Ms. Lund invited Attorney Goldman to weigh in on the difference between 'may' and 'will' and whether it matters. Attorney Goldman advised it does make a difference, noting 'will' is mandatory language, and 'may' is permissive. If CPHS includes the 'will', the reviewer must take the following risk criteria into consideration. Reviewers will not be able to pick and choose the preferred risk criteria. To the extent any of the risk criteria are applicable, the researchers will have to look at them. Dr. Dinis suggested adding 'when it applies' to the sentence, so to capture the spirit of what Dr. Schaeuble said that not all risk criteria will apply. In the case that the risk criteria do apply, the reviewer would assess. Ms. Lund advised that language already exist as noted by Attorney Goldman. Dr. Dinis advised she may have misunderstood, thinking it applied to all cases. Attorney Goldman advised it's implied that if it's inapplicable there would be nothing to review, advising Dr. Dinis' proposal is a good idea, the clarification might be helpful for people to understand when something is or isn't reviewed.

Ms. Lund advised her concern would be that the point of developing the regulations is to take away the arbitrariness of the review across projects to make it fair for everyone. If the criteria exists that all projects submitted with that criteria receive the same review, and if CPHS says 'may' instead of 'will', CPHS is back to a subjective decision which is not fair to the researchers submitting projects.

Ms. Lund suggests the proposed CPHS regulations are not intended for anything that automatically disqualifies a project, CPHS would just gather additional information.

Ms. Lund advised as a committee, CPHS only has purview over the state data. When a researcher wants to link state data with an external data source, if they had an appropriate NPP and considered the risk factors, when they give their data to the other data source, CPHS cannot be responsible for what they chose to do with their data with that data source. Laura thinks CPHS cannot be responsible for ensuring the researchers documentation is correct as long as their documentation is correct and appropriate when they present their information to the state. It is beyond CPHS' purview to consider what researchers do when they're collecting the data under the IPA.

Dr. Dickey asked if CPHS would have the authority to ask for outside data sources to provide the NPP? Ms. Lund answered CPHS could ask for information but would not have the responsibility to consider how other data was collected under the IPA. Dr. Dickey asked if CPHS did not like the NPP, would CPHS have the authority to use their disagreement with the NPP to turn the project? Laura answered CPHS would have a full board discussion about whether it would be appropriate to approve the project in those circumstances.

Dr. Schaeuble advised to focus on what CPHS is trying to protect, which is the people who originally provided the state data. Dr. Schaeuble notes that it makes a difference whether people were given relevant information when their data was collected. It makes a difference to

CPHS reviewers on how CPHS approaches the way researchers attempt to handle the potential risks in their projects. Noting that there is a difference if the data comes from people who have an awareness of how their information will be used, and the potential risks of those uses, or whether there are no risks. Dr. Schaeuble notes that the real focus for CPHS is what the researchers are already planning to do to mitigate risks and what else could they do to mitigate risks where CPHS identifies in the supporting document.

Dr. Schaeuble mentions that he has heard multiple public comments focusing on rejecting projects and suggests that rejecting projects will not be a frequent outcome. CPHS is trying to address and reduce risks.

Ms. Kurtural voiced her primary concern about generative Artificial Intelligence (AI) and the redisclosure of information. Would it make sense for CPHS to revise the first criteria to simply ask the researcher if they plan to use generative AI tools. Dr. Hess agreed generative AI should be a risk criteria because partnerships between academia, Google, and the states are increasing so to identify risk factors for all sorts of this. Researchers are using huge data sets with AI and it's fair for CPHS to ask if the project will be fed into any generative AI models, and to question the extent and purpose.

Ms. Lund expressed concern about CPHS writing regulations too closely tied to a current technology that may be very different in 10 or 15 years from now. If CPHS uses the specific words such as generative AI. That the CPHS regulations will be obsolete in the future. Ms. Kurtural advised there would be a definition for 'generative AI' and regulations could always be changed in the future.

Dr. Delgado advised it's difficult to solve a problem CPHS does not fully understand, like generative AI, which is not in CPHS's scope of expertise. Dr. Delgado is hesitant for CPHS to make decisions that are specifically trying to solve for generative AI.

Dr. Delgado recommended the sub-committee explore Subject Matter Expert (SME) in generative AI.

Dr. Bazzano advised she would love to rely on technologists to be able to make ethical decisions, but if there is an area CPHS is not educated on, then CPHS should educate ourselves. CPHS brings a different perspective then someone who is in technology such a data scientist or a data security expert who are different from ethicists. CPHS can bring in some educators or bioethicists who have expertise or who can teach CPHS about the new field of AI. Even though CPHS has not kept up with generative AI, that does not absolve CPHS from the responsibility. Dr. Bazzano suggest that not all the responsibility should not be placed on people who do not have an ethics background. Dr. Bazzano shares that she has spent time with people who are on the front end of AI in various healthcare capacities, and she advised they are not thinking from an ethical standpoint, and they need CPHS's expertise to do so. Dr. Bazzano recommends CPHS not shy away from it then defer to other people who don't have a background in ethics.

Dr. Dinis agrees as AI can tie different data together, and the data is always in the background, getting gathered and stored with not knowing who has access to it. Dr. Hess asked if it would be possible to get a SME in AI so when CPHS receives an IPA application which proposes AI, then the application would automatically go to full board review and a discussion with the SME.

Ms. Kurtural advised obtaining an SME is completely possible but there has to be a threshold for the application review process? Will the researcher use generative AI tools or not? The committee agreed that these questions should be embedded in the application.

Dr. Dickey advised CPHS has requested a data security person for a long time, even before AI, and have not been able to get anybody. Ms. Kurtural advised their department is starting a training in January on AI and she can loop CPHS in, as the training is internal to the state.

Ms. Lund summarized the direction for the sub-committee would be to add language around generative AI to the list of risks. As for the criteria, CPHS moves forward with the final word smithing with the third option.

Ms. Lund opened the discussion up for public comment. (1:24

Agnes Balla provides a public comment via zoom virtually. Ms. Balla thanked the committee for having her. “I work for the University of California Office of the President. I work in the Research Policy Office and my role is to work broadly across our UC campuses with our research administrators on a range of issues. I work closely with IRB directors at all of our campuses to make sure that we are on the same page about what the regulatory requirements are, talk about best practices and shared experiences, and problem solve among the group. One of the concerns that we as a group have been discussing as CPHS continues to kind of roll out its framework is the concern that the role of CPHS is being muddled between its IRB hat and its IPA hat. With this expanded criteria being proposed, and in listening to today’s discussion, I have a lot more questions and concerns about that muddling of that role. As I understand it, CPHS serves as the IRB for CalHHS for any studies that are supported or funded by them, and separately it has a role that is designated under the IPA. That talks about the need for making sure that state-held data is handled appropriately and that is the review that CPHS conducts under the IPA role. But much of the discussion that I heard today wasn’t around that, right? It wasn’t around the IPA. It was, you know, as Dr. Schaeuble noted, about the protections of those whose data is being used, the ethical considerations. And that is an IRB role. And the reason this brings me a lot of concern, or at least more questions than anything else, is because our researchers here at UC are going to be going to their own IRB to get review, and they’re mandated to go to CPHS to get an IPA review. But that is more sounding like an IRB review. So this sounds very duplicative of those efforts. And what happens in those cases? You know, there is a push on the federal end, particularly for federally funded studies to get a single IRB review. And how do we match up those requirements with now what seems like a duplicative IRB review? And so I have a lot of questions about how that’s going to be managed. If this effort moves forward because it really just sounds like an IRB review. And if that’s the case, then I think we need to be upfront about that, right? Is that now all IPA studies are being pushed into an IRB review by CPHS. And then should we be coming up with, you know, reliance agreements, or MOUs for all these studies that now need to get an IRB reviewed by the State, and perhaps not by our own campuses. So, a lot of questions on that. The generative AI discussion that I heard today. I know that we have been struggling with that quite a bit. And you know you said that if you do want an expert, I’m not an expert, but I can tell you about some of the experiences that we’ve had, and I’m happy to share those. Just to give a very specific example, something that we’ve been working on is, as some of you might be familiar, NIH updated their certificate of confidentiality rules about what’s required when getting COC. And one of those is we as an institution have to assure that any third parties that we’re working with do not further disclose information that might be available to them, right? So one of the things that we’ve been talking about is Zoom, for example. So, using Zoom in conducting interviews, how do we protect that information? And so there are actually things that we have implemented

to meet our own obligation as the institution to protect that information according to the COC standards and I'm happy to share what we've done separately. I know my public speaking time is limited here, so I won't do that, but I can follow up if that's helpful. But I do want to be very careful about including generative AI in such a proposal. Because what is gen AI, you know, when I use Google? Now, we get that little summary of, you know, here's what the whole world wide web has to offer. And that's gen AI, so if I'm using Google, do I now, is that something that's going to be part of the application consideration, right? So I do want to be very cautious about how this is brought forward. I will also just mention that the State has sort of other requirements, including under Assembly Bill 302, and a separate executive order that Newsom passed around the use of Gen AI. And, particularly, we'll also have to report that when anytime that we get state funding, and I'm happy to provide more information on some of those other requirements in case the committee is not familiar with them. But again, I think one thing I do caution is not to create duplicative reviews or duplicative requirements that already are existence, because I think that just provides a whole lot more confusion to everybody. Thank you very much. I appreciate the opportunity to get to talk about this, and I'm happy to provide my support in any way that would be helpful to the committee."

Dr. Delgado thanked Ms. Balla for her comment, advising CPHS would reach out to her about generative AI, and the more information shared the better as everyone seems to be struggling with generative AI. The floor closed for public comment.

Motion: It was moved by Dr. Schaeuble and seconded by Ms. Lund for:

1) **The Full committee to endorse as a threshold for requesting additional information focusing on those studies which involve any of the risk criteria enumerated in the draft document.**
2) **The full committee asks the subcommittee to work with legal council to make any further revisions necessary in the draft document.**
3) **The full committee asks the subcommittee to work with Legal Counsel to find an appropriate way to include possible uses of gen AI or similar technology as an example of additional risk in IPA studies.**

Approve: Dr. Schaeuble, Ms. Lund, Dr. Dinis, Dr. Hess, Dr. Johnson, Ms. Kurtural. Dr. Palacio, Dr. Ventura

Oppose: Dr. Dickey
Abstain: None.
Absent: Dr. Azizian, Dr. Ruiz, Dr. Bazzano, Dr. Dinis.

Total=9 In Favor-8, Opposed-1, Abstained-0

Dr. Dickey opposed since he believes the criteria for all three parts of the motion are too broad.

Dr. Delgado suggested Ms. Lund provides the next steps for the sub-committee. Ms. Lund advised the sub-committee is scheduled to meet in January 2025. The sub-committee will take the motion back and work to have the revised version ready for the next CPHS full board meeting in February. Dr. Delgado thanked the sub-committee for their work and the public for their comments.

D. Review and Approval of Meeting Minutes

No public comments in-person or virtually for the August 2, 2024, meeting minutes.

Motion: It was moved by Ms. Lund and seconded by Dr. Dickey to approve the August 2, 2024, meeting minutes.

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

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

No public comments in- person or virtually for the September 13, 2024, meeting minutes.

Motion: It was moved by Ms. Lund and seconded by Dr. Schaeuble to approve the September 13, 2024, meeting minutes.

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

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

E. Projects with Reported Adverse Events and/or Deviations

None.

F. New Projects – Full Committee Review Required)

1. Project # 2024-149 (Johnson)
Title: Social Determinants of Health Survey Among African American Prostate Cancer Survivors
PI: Chanita Hughes Halbert, PhD
Co-PI:
Board Decision: Approved

Discussion:
This project has been aimed at understanding quality of life and social issues among African American men with a personal history of prostate cancer who had been treated with radical prostatectomy. Prostate cancer is one of the leading causes of morbidity and mortality, particularly among African American men. The study focuses on how social determinants of health—including neighborhood deprivation, experiences with social isolation, financial strain, and perceived stress—influence quality of life specifically among African American men with prostate cancer.

The primary research questions center on the nature and distribution of social issues and social risk factors among this population, as well as the associations between social background, sociodemographic characteristics, and clinical characteristics in relation to quality of life and social issues. The study proposes establishing an observational cohort, which involves collecting self-reported data on social determinants of health, clinical experiences, and quality of life. Recruitment is planned through the Los Angeles Cancer Surveillance Program.

Eligibility criteria included African American men, either self-identified or identified using registry data, who had been diagnosed with prostate cancer and had completed a radical prostatectomy. Evidence-based recruitment strategies from previous research are to be utilized for enrollment into the study. Participants will be asked to complete a structured survey using validated instruments and questionnaires to measure quality of life, social isolation, and perceived stress. Clinical data will also be abstracted using the CSP case report and recorded in the study database. All data will be de-identified. Appropriate statistical analyses will be employed to address the study aims.
Dr. Johnson, the primary reviewer, updated the committee that the study had undergone multiple revisions. She clarified that the research team made two main revisions in the latest version in IRBManager. First, they removed certain items from the questionnaire that addressed victimization. In the new submission, these items were eliminated, and adequate mentions and resources were provided to participants in case they felt distressed from participating in the study and responding to those questions.
Second, the team initially included a modality where participants would mail back their questionnaires and requested a waiver of written informed consent. They later removed the mailing back option. Now, participation is through phone and questionnaire submission via Redcap. For the Redcap method, they planned to collect written consent from participants but still requested a waiver of written consent for the phone method. Given these modifications throughout the application, Dr. Johnson expressed her satisfaction with the proposal's current state and opened the floor to the committee for any additional concerns.

Dr. Ventura inquired whether verbal consent would be obtained for phone submissions, to which Dr. Johnson confirmed that for phone interviews only written consent was waived, not informed consent.
Dr. Dickey raised concerns about the consent form's mention of accessing cancer registry data. The researchers confirmed that the informed consent form specified the collection of clinical variables from the cancer registry and that a brochure explaining data collection would be included in the mailer. Dr. Johnson outlined the procedure: the cancer registry would provide recruitment information, assign IDs to consenting participants, and link these IDs to release medical information, ensuring no additional medical data was released for non-consenting individuals. Dr. Dickey emphasized that merely including the cancer registry brochure was insufficient; the consent form needed to explicitly mention data access. The principal investigator confirmed this inclusion. Dr. Dickey also asked about the distribution method of gift cards to participants. The researchers explained that, upon survey completion, participants could choose to receive an electronic gift card via email or a physical card by providing their mailing address.

Dr. Hess inquired about the composition of the final annotated dataset, questioning whether it combined cancer registry data with survey data. The principal investigator clarified that the de-identified dataset would include self-reported survey data along with clinical information obtained from the cancer registry.

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

Approve: Dr. Johnson, Ms. Lund, Dr. Dickey, Dr. Hess, Ms. Kurtural, Dr. Palacio, Dr. Ventura.

Oppose: None.
Abstain: Dr. Schaeuble.
Absent: Dr. Azizian, Dr. Ruiz, Dr. Bazzano, Dr. Dinis.

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

Dr. Schaeuble abstained since he stepped out at some time during the discussion.

2. Project #	2024-183 (Lund)
Title:	Priorities, Preferences, And Tradeoffs Among Older Adults With Oropharyngeal Cancer
PI:	Evan Graboyes, MD, MPH
Co-PI:	Ashish Deshmukh, PhD, MPH
Board Decision:	Approved Pending Conditions - Designee Review

Discussion:
The study is aimed to understand patient priorities and preferences among individuals with human papillomavirus (HPV)-related oropharyngeal carcinoma, a rapidly increasing cancer, particularly among older adults in the United States. This demographic shift has necessitated a reevaluation of survivorship and treatment strategies, especially considering that older adults were underrepresented in clinical trials focusing on treatment de-intensification.

The researchers have proposed utilizing data from the California Cancer Registry (CCR) to recruit participants and gather their demographic and clinical information. They have planned to collaborate with the CCR to identify individuals treated for HPV-related oropharyngeal cancer within the past five years. The recruitment process involves initially sending these individuals a letter detailing the study, accompanied by the appropriate CCR pamphlet and documentation explaining the study's rationale and procedures. Subsequently, the team has planned to contact participants by telephone. After obtaining written informed consent through a remote video teleconference, participants would complete two questionnaires: a standardized 12-item patient priority scale and a standardized behavioral economics assessment known as the Standard Gamble (SG), which explores patients' trade-offs between certain outcomes and the associated risks they would accept. The study procedure, will be conducted by trained staff, has been designed to take approximately 30 minutes, and participants will receive $50 as compensation for their time.
California is one of three registries across the United States involved in this recruitment effort. For the California-specific portion, the researchers targeted 50 eligible participants and requested 250 cases from the CCR to achieve this goal. In addition to recruitment, the team has planned to comprehensively characterize their clinical sample by collecting relevant demographic and clinical characteristics from the patient population. They have included their statistical analysis plan and the justification for the selected variables in their written procedure.

Ms. Lund, the primary reviewer of the study, informed the board of several key points. She noted that, as the principal investigator, Dr. Graboyes had mentioned that the study was multi-

site, involving registry data from various state cancer registries, each governed by different statutes. Initially, the application was not specific to the California Cancer Registry (CCR). Ms. Lund requested revisions to ensure adherence to California protocols, which were subsequently made, aligning the recruitment strategies with California's requirements.

She also highlighted that the Institutional Review Board (IRB) overseeing the entire project was the one at the Medical University of South Carolina (MUSC), where Dr. Graboyes is affiliated. Ms. Lund expressed a desire to discuss this further, particularly concerning the consent form. She acknowledged that the original notification letter was written at a higher grade level but had been revised to a more appropriate level, with which she was now comfortable. The full script intended for the teleconference had been provided, and she had no issues with the questionnaire. Since there would be no audio or video recording, additional recording information in the consent form was unnecessary. Ms. Lund felt that all her concerns had been addressed, except for those related to the consent form, which she wished to discuss with the board.

She found the initial consent form confusing, as it referenced health records not pertinent to the study and mentioned MUSC, which was irrelevant for California participants. This could potentially confuse participants from California. There were also minor issues stemming from the standard MUSC consent template. Dr. Graboyes agreed to collaborate with his IRB to remove language specific to MUSC health records that did not apply to California participants. Although a final version of the consent form was not attached to the application, proposed revisions had been emailed for review.

Ms. Lund expressed concern about potential delays if disagreements arose with the other IRB over language deemed inappropriate for California. She noted that the consenting process involved direct interaction, allowing participants to ask questions, which could mitigate confusion over irrelevant references, such as to MUSC health records. She suggested that if Dr. Graboyes could not secure approval from his IRB to amend the standard language, the consenting process would still protect participants. Therefore, she recommended the board approve the project, with deferred approval pending the extent of possible changes to the consent form after discussions with the other IRB. She then opened the floor for questions and comments.

Dr. Dickey inquired about the specific issues with the consent form. Dr. Delgado mentioned that the issues referred to the inclusion of health records, which is standard consent language for MUSC, and the exclusive mention of MUSC. Ms. Lund agreed, noting that references to health records and MUSC health records could confuse California participants, leading them to question the relevance.

Dr. Schaeuble observed that the researcher aimed to remove substantial sections of the consent form specific to his institution and asked about the IRB's willingness to implement the proposed changes. Dr. Graboyes expressed confidence in the IRB's accommodating nature, citing positive experiences with multi-institutional studies. He believed the rationale for avoiding patient confusion was sensible and anticipated the IRB would agree to exclude irrelevant consent components.

Dr. Schaeuble appreciated the reassurance, noting that the requested changes seemed straightforward and hoped the alternative approach wouldn't be necessary.

Dr. Delgado remarked on the frequency of such issues in multi-site studies and agreed with Ms. Lund's approach to facilitate progress and avoid delays.

Dr. Ventura inquired whether the years of data requested from the California Cancer Registry (CCR) had been clarified in the application, noting it was among Ms. Lund's comments and expressing uncertainty about its inclusion in the revisions. Ms. Lund responded that all data requests had been clarified to her satisfaction, with no outstanding issues. She explained that initial confusion arose because a supporting document in the first submission contained information differing from the protocol, but that document had since been removed, resolving the issue.

Dr. Graboyes, the Principal Investigator, acknowledged the oversight, apologizing for any confusion caused by the inconsistent documents. He assured that the current version was more internally consistent and coherent. He added that, in addition to integrating multiple pieces of registry data, a separate part of the grant involved using the registry data. He confirmed that the data in question spanned from 2019 to the present, with "present" defined as the date the information reached the CCR.

Dr. Dickey asked if a central Institutional Review Board (IRB) was involved in the study. Ms. Lund confirmed that the Medical University of South Carolina (MUSC) IRB served as the central IRB. Dr. Dickey noted the interesting interplay between federal and state laws, stating that while federal law might suggest deferring to the central IRB, the Information Practices Act and CCR's statutory requirements necessitated their own review. Ms. Lund agreed, emphasizing that CCR required statutory review.

Dr. Dickey suggested examining the regulatory issues further, acknowledging the necessity of reviewing the project under the Information Practices Act. He questioned whether changes to the consent form were appropriate under this type of review. Ms. Lund clarified that the current review was under the Common Rule, reiterating her earlier point about not wanting to delay the project if the MUSC IRB declined to make the requested consent form changes. She proposed deferring to the MUSC IRB in such cases, referencing her initial recommendation to motion for project approval, including deferred approval pending Dr. Graboyes' efforts to modify the consent form in collaboration with the other IRB.

Motion: It was moved by Ms. Lund and seconded by Dr. Johnson to grant a deferred approval, one-year, minimal risk pending the following specified revision which require expedited review and approval by a CPHS subcommittee of Ms. Lund

—The final version of the consent form will be attached to the protocol

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

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

3. Project # 2024-189 (Dickey)

Title:	Patient Perspectives on Relabeling and Pathology Reporting for Grade Group 1 Prostate Cancer
PI:	Matthew Cooperberg, MD
Co-PI:	Scarlett L Gomez, PhD Stacy Loeb, MD
Board Decision:	Approved Pending Conditions - Designee Review

Discussion:
Grade Group 1 (GG1) prostate cancer, a low-grade form of the disease, has long been a public health concern. While screening and managing high-grade prostate cancer have saved many lives, these efforts have also led to significant overtreatment of low-risk cases. Evidence suggests that GG1 prostate cancer may be a normal aspect of aging, as autopsies reveal its presence in about half of all men who live long enough. Molecular studies indicate that GG1 is genetically similar to normal adjacent tissue. The overdiagnosis and overtreatment of GG1 have hindered effective screening and exacerbated disparities in prostate cancer outcomes.

There is a growing call to rename GG1 prostate cancer to better reflect its nature. Various precancerous labels have been proposed over the past decade, gaining traction recently. A symposium held alongside the American Society of Clinical Oncology Genitourinary (ASCO GU) annual meeting brought together 50 participants from four continents, including experts in urology, radiation oncology, primary care, epidemiology, and patient advocacy, as well as a representative from the CDC, to discuss this issue.

One concern raised was whether patients would take the diagnosis seriously if the terminology changed. Current guidelines recommend active surveillance for GG1 prostate cancer, monitoring the condition and treating only if it shows signs of becoming more aggressive—a process that can take years or even decades. However, some men eventually develop higher-grade cancer that requires treatment. Active surveillance has increased from 25% a decade ago to about 60% today, but this is still considered too low, with significant variation among practices. Overtreatment of low-grade disease remains common. There is concern that removing the “cancer” label might lead patients to neglect necessary follow-ups, such as prostate-specific antigen (PSA) tests and biopsies.

Aim one of the study consists of qualitative studies which include recruiting patients from the California Cancer Registry (CCR), with an emphasis on Black and Hispanic men—groups that bear a disproportionate burden of lethal prostate cancer and have been underrepresented in research. Focus groups will explore reactions to the diagnosis, understanding of active surveillance, and the potential impact of removing the term “carcinoma” from pathology reports. Feedback on pathology reports and information presentation will also be collected.

Aim two consists of quantitative survey, including an online survey of 525 patients, also recruited from CCR, to assess anxiety levels, preferences for surveillance versus treatment, and reactions to alternative pathology report formats. This will help determine how different terminology might influence decision-making at diagnosis and during the surveillance process.

Dr. Dickey inquired about the recruitment and consent processes. Dr. Cooperberg explained that patients would be identified through the California Cancer Registry (CCR) by the University of California, San Francisco (UCSF) team, which had substantial experience in this area. Patients would be approached in writing or by phone, with up to three callbacks, based on their diagnosis of Grade Group 1 prostate cancer recorded in the CCR.

Dr. Dickey asked about the number of patients to be contacted and the specific information to be obtained from the CCR. Dr. Cooperberg stated that for the qualitative focus groups, the goal was to assemble six groups, each with four to six participants, including at least two conducted in Spanish and the others in English. He confirmed that data requested from the CCR would include basic clinical information to confirm the low-grade diagnosis and low-risk status, such as stage, PSA levels, and extent of biopsy core involvement.

Dr. Dickey questioned the necessity of information beyond contact details, and Dr. Cooperberg affirmed the need to ensure participants met the eligibility criteria.
Regarding the consent form, Dr. Cooperberg expressed a preference for a waiver of written consent, citing the low-risk nature of the research and its alignment with federal criteria, and anticipated approval for verbal consent.

Dr. Dickey noted the inclusion of a flyer in the application and questioned its necessity. Dr. Cooperberg acknowledged that it might have been carried over from previous studies and confirmed that recruitment would be through the registry.

Addressing the use of questionnaires in addition to focus groups, Dr. Cooperberg explained that the survey for aim two would be developed and refined based on insights from the focus groups and interviews. Dr. Dickey mentioned a screening questionnaire administered before the focus groups to gather demographics and other information, which Dr. Cooperberg confirmed, stating that its purpose was to validate registry data.

Dr. Dickey emphasized that this screening occurred after obtaining information from the registry and before conducting focus groups, with the consent form involved at that stage. He suggested that the consent form should explicitly state that the study pertained to low-risk prostate cancer. Dr. Cooperberg agreed to incorporate this clarification.

A research staff clarified that the team intended to submit patient-facing materials for the qualitative one-on-one surveys following the focus group activities. These materials had been included with the application. After completing the qualitative study, the team planned to submit materials for the larger quantitative survey. She clarified that the questionnaire for focus group participants was a brief demographics survey, which had been attached to the application.

Dr. Schaeuble noted that the registry had agreed to release most of the requested data variables but required strong justification for releasing census tract information. He inquired about the necessity and status of this information.

Dr. Cooperberg responded that census tract data would be more critical for the second phase (Aim 2) of the study. The team planned to geocode patients' locations to derive parameters related to social and structural determinants of health, leveraging the UCSF group's extensive experience in this area. While less critical for the smaller focus groups, this information would help identify predictors of anxiety and preferences, ensuring representation across California's geographic regions. Neighborhood factors and structural determinants could be assessed using this data, making it more vital for the second phase.

Dr. Schaeuble asked how the geocodes would be utilized and what additional information might be obtained regarding participants' neighborhoods.

A research staff member explained that census tract and block group numbers were necessary for appending geospatially referenced data measuring structural and social drivers of health. This information would remain confidential within the authorized study team. Further justification had been provided to the California Cancer Registry (CCR), which had agreed to the request.

Dr. Schaeuble questioned whether this implied future linkage to other data connected to participants' geographical information.

Dr. Cooperberg confirmed that the UCSF team, including Scarlett Gomez and Iona Chang, had developed and validated numerous neighborhood-related parameters, such as historical redlining and access to quality food. These structural and social determinants significantly impact prostate cancer outcomes. While not patient-level or identified data, these factors affect both diagnosis and disease progression through mechanisms still under investigation. The team had pending grant proposals to explore these mechanisms further. The data would be used to incorporate neighborhood-level information, not patient-level details.

Dr. Schaeuble found the approach reasonable and expressed a preference for clarification on the additional variables before that part of the study started. Dr. Cooperberg mentioned that the group had published studies using this methodology, referenced in the grant proposal, and offered to append them to the protocol if desired.

There was no public comment on this discussion.

Motion: It was moved by Dr. Dickey and seconded by Ms. Lund to approve the project as minimal risk, with a continuing review in one year, and it was clarified that the current approval only covered the focus groups and their associated questionnaires, with an amendment to be provided for the development of one-on-one interviews and the survey.

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

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

G. Full Board Continuing Review

None.

H. Amendments – Full Committee Review Required

1) Project #	2024-094 (Hess)
Title:	Tracking Health and Responses to Living with Cancer (THRIVE Study)
PI:	Arnold Potosky, PhD
Co-PI:	Anshu Shrestha, PhD, MPH
Board Decision:	Approved Pending Conditions - Designee Review

Discussion:

Dr. Hess provides background to the committee regarding this project is requesting an amendment. The approved protocol is a project looking at patient reported outcomes in individuals with metastatic colorectal cancer. Dr. Hess requested a full board review since this protocol submitted an amendment for a new human subject data collection activity to be added into this project.

Dr. Hess thanked the research team for the clarification and explanations of the amendment to the way the research team will be identifying eligible cases. Dr. Hess noted she still had some question's on how to the research team will identify eligible cases and requested the Principal Investor, Dr. Anshu Shrestha, provide a quick run down on the end of day assessments the researchers are proposing to add to this protocol.

Dr. Shrestha highlighted that the amendment being requested is requesting two main changes to the approved project. The first change being requested is how the researchers are identifying eligible cancer cases for contact. In the approved project plan, the researchers were planning on using the registry data at a more refined form. However, during that process Dr. Shrestha learned about the delay in reporting and became concerned she will not be able to identify enough eligible individuals for the study. Dr. Shrestha is now proposing a different approach in which she still relies on the registry data, but instead of relying on the processed data, the research team will work closely with the Cancer Registry of Greater California (CRGC) to flag eligible patients early in the process. In the approved protocol, the research team during the cancer reporting, will receive pathology reports first that sit for many months before they get processed. The change being requested would allow the researchers to not be involved in that process but rely on the cancer registrars who provide this process to prioritize certain colorectal cancer patients who could potentially be eligible for this study.

The second change being requested is after enrolling participants and they have completed the baseline and opt for electronic method of contact for future surveys. The research team will send out the quick 5-minute end of day assessment in a subset of participants. The goal is to select and collect data from up to 80 participants. In the amendment it stated 160 participants since this is a multi-site study and are looking to collect data from up to 80 participants from California. Dr. Hess suggested that one change for this amendment is amending the reporting the number of participants from California to reflects that. Dr. Hess asked for clarification regarding the pathology reports and the process of processing them within California Cancer Registry (CCR). Dr. Shrestha explained the data is coming into the registry, but during that process there is a step that happens, the registrars screen those pathology reports and identify whether they're reportable or not reportable. This information they are proposing to gather is in the upstream of the data processing.

Ms. Lund questions if whether the researchers have in law the authority to use these pathology reports. If they have authority in law to use data that's abstracted from reports in various sources. Ms. Lund suggests having a legal opinion from CCR on whether those pathology reports are truly CCR data in their pathology report form. Dr. Shrestha provides clarification through the process of coding and flagging the initial screening of the pathology reports by the registrars, is part of the process for CCR. Our research team are not going to be using the pathology report itself but relying on CCR have finished the first couple of steps of the data processing. Dr. Hess agrees with Ms. Lund there is clarification needed if that data is legal to release, or does the data have to be fully ingested and processed into CCR before it becomes part of the data that can be legally released. Dr. Shrestha agreed for the committee to reach out to CCR to get confirmation. She did note that at the registry, for patient contact studies, they often use data that has been fully or partially processed in the registry.

Dr. Delgado suggested proceeding to other aspects of the protocol to have the committee get to a point they feel comfortable approving, pending a decision from CCR so the project does not have to come back to the full committee for review.

Dr. Dickey questioned if the researchers could come back with a LOS or if they would need a legal document from CCR. Dr. Hess suggested the Letter of Support (LOS) would be sufficient since the LOS states that the data release is legal and meets all the requirements needed. Ms. Lund reminds the committee that CCR will not submit a LOS for an amendment and suggests reaching out to CCR to ask specifically if this release of the data is legal. Dr. Hess requests the research team to reach out to CCR for clarification by sharing the amendment protocol with CCR. Once the researchers receive feedback from CCR to share it with Dr. Hess, the primary reviewer of this protocol.

Dr. Hess notes that the researchers are proposing to contact the patient physician as well contacting the patients in advance. Dr. Shrestha noted that was in the second approach of the amendment since her understanding of the California State Law is that the second approach is considered a rapid case ascertainment in the registry world. Using this approach for identifying eligible patients that they need to notify the physicians ahead of contacting the participants.

Dr. Shrestha asked the expectation for how should inform CPHS on the response's they receive. Dr. Hess informed Dr. Shrestha she can forward the responses to her email or cc her in the email just in case CCR has any questions or push back Dr. Hess can inform CCR it was a request from CPHS.

Dr. Hess clarifies the end of day assessment is only for participants that opt in to be contacted electronically and not all the participants in the main study. Dr. Shrestha confirmed that was correct.

Motion: Dr. Hess moves and Ms. Lund seconds the motion for a deferred approval, on year minimal risk provided that the research team:

1) Share the amended protocol with CCR and provide the Board with written confirmation that CCR supports the release and use of pathology reports from the Registrars and that this is in fact legal.

2) Revise the number of participants to 80 California participants for the end of day assessments.

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

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

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 (20)

K. 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 (85)

K1. 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 (18)

L. 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 (10)

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 (10)

P. Public Comments

Dr. Hess asked if there is any update for the board on CPHS collecting fees. Dr. Rykaczewska advised that the administrative team is still working on crunching the numbers and there should be an update in the spring.

Q. Next Meeting

The next CPHS meeting is scheduled to be held on Friday, February 7, 2025.
The next CPHS subcommittee meeting is scheduled to be held on Friday, January 10, 2025.

R. Adjournment

This meeting was adjourned at 11:32 AM on December 6, 2024.