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, July 12, 2024
8:30 a.m.

Zoom:
CPHS July 12, 2024, Full Committee Meeting

Meeting ID: 160 358 6546
Passcode: 076059

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

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Meeting ID: 160 358 6546

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
Philip Palacio, EdD, MS
Juan Ruiz, MD, DrPH, MPH
Darci Delgado, PsyD.
Alicia Bazzano, MD, PhD
Laura Lund, MA
Maria Dinis, PhD, MSW
Allen Azizian, PhD

Alternate Member
Millard Murphy, JD
Lois Lowe, PhD

CDII
John Ohanian, Director
Agnieszka Rykaczewska, Deputy Director
Jennifer Schwartz

CPHS Administrator
Agnieszka Rykaczewska

Committee Members Present in Person:

Larry Dickey, MD, MPH
John Schaeuble, PhD, MS
Maria Ventura, PhD
Jonni Johnson, PhD
Carrie Kurtural, JD

Committee Members Present Remotely:

Philip Palacio, EdD, MS
Juan Ruiz, MD, DrPh, MPH
Darci Delgado, PsyD.
Alicia Bazzano, MD, PhD
Laura Lund, MA
Maria Dinis, PhD, MSW
Allen Azizian, PhD

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

Center for Data Insights and Innovation Staff Present Remotely:

Jennifer Schwartz, Chief Council

California Health and Human Services Staff Present in Person:

Jared Goldman, General Council
Maggie Schuster, Attorney
Francis Brown

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

James Yi

A. Welcome

a) Chair Updates

Dr. Delgado thanked the committee members for willingness to meet more frequently to address administrative items that have been pending for the last six to nine months. Since Dr. Delgado is attending remotely for today's meeting, she asked Dr. Dickey to lead today's meeting. Dr. Dickey agreed to do so.

Agnieszka Rykaczewska, CPHS administrator, informed the committee that the Bagley keen, Open Meeting Act requires a majority of members attend in person to have quorum. However, the act includes some criteria where if the member is not able to attend in person, for reasons that meet that criteria and inform the administrator prior to the meeting, that member can attend remotely while being counted toward the quorum. Ahead of this meeting, Dr. Ruiz and Ms. Lund

informed the CPHS Administrator that they would attend remotely, and their criteria satisfied those requirements of the Bagley Keen, Open Meeting Act.

B. Administrator Updates

a) Review of March Meeting Minutes

Agnieszka Rykaczewska informed the committee members that the March meeting minutes were omitted from the June package by mistake. As they were not examined during the June meeting, these minutes have been included in the package distributed for today's meeting. Agnieszka Rykaczewska also mentioned that Dr. Schaeuble had proposed some amendments to the minutes, which have been forwarded to the committee, highlighting the changes, and providing a revised clean copy.

Motion: Ms. Kurtural moved, and Dr. Ventura seconded the motion to approve the March 1, 2024, meeting minutes.

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

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

C. Introduction to the IDEA/BUCP and discussion of whether these may stand in for Letters of Support (LOS)

Dr. Dickey introduced Attorney Jennifer Schwartz, CDII general council to provide some context on the Interagency Data Exchange Agreements (IDEA) and the Business Use Case Proposal (BUCP) and if she would recommend having it serve as the letter of support from departments. Attorney Schwartz provided an overview on why the state has come up with the IDEA and BUCP. The issue the state was running into was that interagency agreements to share data between departments were taking years to complete. The state created the IDEA that streamlines the process with data sharing within state departments, providing high-level terms and conditions for all the departments. The BUCP details the project or programmatic work that requires that data. Together, the IDEA and the BUCP encompass the entire agreement between departments for sharing and exchanging data.

Attorney Schwartz explained that the BUCP contains all the details regarding the projects, including data use, data elements, formatting and presenting the data, terms of sharing the data, data destruction , and any special security and privacy requirements. Social Security data would be an example of data that has specific requirements in law. The BUCP is formed in a process where the programs and the department discussed and documented in detail the project and the need for the data. After the BUCP is created, it is sent to legal, privacy, and security departments, and is approved by a manager with the authority to sign on behalf of the department. The BUCP process ensures legal justifications, lawful data sharing, and secure protection of data. While a research review process often involves a committee of legal, Information Security Officer (ISO), and subject matter experts in the research principles, it evaluates if the research is valuable, ethical, lawful to share the data, and assesses risks to individuals' data.

The IDEA and BUCP can be used for research. However, the process of approving a BUCP by a department does not go through the research review process, it goes through a separate data release process focused on legality of sharing data and ensuring its protection

Attorney Schwartz suggested considering a letter of support from the department to ensure the department has reviewed the research proposal since the BUCP only focuses on lawful data sharing security..

Ms. Lund provided insight into the specific information she seeks in the Letter of Support, emphasizing the need to verify if the department is willing to release the data for the projects being reviewed and if the department's data release complies with all applicable laws. Attorney Schwartz pointed out that the BUCP lacks the universal terms and conditions, which include the restrictions, terms, and conditions governing data usage. This missing information can be found in the interagency data exchange agreement, which all departments have agreed to. The IDEA confirms that the department will adhere to all laws and state policies. Together, the BUCP and the IDEA constitute the complete agreement.

Attorney Shwartz suggested gathering a letter of support as a formal acknowledgement that the department has examined the research proposal through a research review lens rather than a data release lens.

Dr. Dickey suggested amending the policies and procedures to state that Letters of Support should be provided for all projects, even if BUCPs are provided. Ms. Lund agreed with Attorney Shwartz's suggestion to require researchers to submit the Letter of Support to ensure the departments releasing the data have reviewed the research proposal and are promising that the release of the data complies with all laws.

James Yi, an attorney for the Department of Healthcare Access and Information (HCAI) provided public comment to the committee noting that some statutes require HCAI data to be made available to public health. The statutes do not allow HCAI to alter or control how public health uses that data. James noted that the statue indicates that public health has all the responsibility to comply with the requirements of CPHS. James noted that there might be some statutes that prevent the departments from providing a letter of support.

Attorney Goldman suggested letting the motion stand and connecting with James to look more into the specific statues. If any clarification is needed Attorney Goldman will inform the committee at the next meeting.

Motion: Ms. Kurtural moved, Dr. Schaeuble seconded the motion to have all research projects to require letters of support from all departments who are the original owners of the data being requested, and a BUCP does not satisfy that requirement.

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

Total= 11 In Favor- 11, Opposed- 0, Abstained- 0

D. Overview of HIPAA Waivers and discussion of CPHS approach

a) Overview of HIPAA Waivers and review of statutory authority

Dr. Dickey raised a concern with the committee that the HIPAA waiver approval letters issued by CPHS do not comply with the federal guidelines. The Federal law mandates that CPHS must specify all the data being waived, along other necessary criteria, in the HIPAA waiver approval letter.

Dr. Dickey requested that CPHS Staff present the proposed HIPAA waiver approval letter to the committee, noting it includes all the federally required criteria.

Attorney Jared Goldman is to review the proposed HIPAA letter and collaborate with CPHS Staff on any necessary revisions.

b) Discussion of CPHS approach to HIPAA Waivers

Dr. Dickey referred to the federal law where it states HIPAA waivers can be granted by an IRB operating under the common rule and or by a privacy board. He noted that the privacy board is not bound by all the components of the common rule. Dr. Dickey also mentioned that most of the HIPAA waivers being granted are for Information Practices Act (IPA) reviews since they are data only requests. He raised the question of how CPHS can approve HIPAA waivers for an IPA review if CPHS is not operating under the Common Rule.

Dr. Dickey reviewed the federal law with Attorney Goldman and noticed that numerous other IRBs operate as both an IRB and a privacy board. After discussions with legal counsel, it was confirmed that the requirements for an IRB satisfy the requirements for a privacy board, since the privacy board's standards are much less stringent than those for IRBs.

Attorney Goldman confirmed that CPHS meets all the requirements under the HIPAA Privacy Rule and had no concerns with CPHS acting as a privacy board for the purpose of granting HIPAA waivers of authorization.

Ms. Kurtural agreed with CPHS acting as a privacy board and recalled that certain departments, such as Department of Health Care Services (DHCS) and Department of Developmental Services (DDS), have contracts reflect that these boards act as a privacy boards when HIPAA waivers are needed.

Attorney Goldman clarified that no vote is needed for CPHS to act as a privacy board. Dr. Dickey asked whether some language should be added to the CPHS website, indicating that CPHS serves as the privacy board for the California Health and Human Services (CalHHS). Ms. Kurtural noted that adding such language to the CPHS website would enhance regulatory standpoint and provide clarification to researchers.

c) Discussion and review of updated HIPAA Waiver Approval Letter

Dr. Bazzano requested examples of when the HIPAA waiver would apply under a privacy board rather than under the Common Rule. Attorney Goldman explained a simple example: if there is a request for the disclosure of Person Identifiable Information (PII) for the purpose of research and an express exemption to the Common Rule where an IRB review is not required.

Dr. Dickey explained that if CPHS is approving research protocols under the IPA, then CPHS has the ability to grant a HIPAA waiver under a privacy board. Dr. Dickey noted that this was brought to the attention of the committee, because recently, the Department of Healthcare Services (DHCS) was requesting a HIPAA waiver from CPHS and not their internal IRB. In the past CPHS could not do that since the protocol was not reviewed under the Common Rule, but now CPHS reviews the protocol under a privacy board and provides the HIPAA waiver.

Ms. Lund asked for clarification on granting a HIPAA waiver for a protocol that CPHS reviews under the IPA but not under the Common Rule criteria. She questioned whether the IRB reviewing the protocol under the Common Rule would be the entity to grant the HIPAA waiver. Ms. Lund noted that she does not feel comfortable granting a HIPAA waiver if she has not reviewed the protocol under all the criteria and only reviewed it under the IPA. Dr. Dickey and Ms. Kurtural explained that the criteria for HIPAA Authorization are extremely similar to the IPA, almost mirroring it. Both the HIPAA Authorization and IPA require minimal risk and the use of minimum amount of data necessary to accomplish the research purposes. Ms. Kurtural suggested that departments contract with CPHS since CPHS reviews the same criteria when reviewing a research project. She also suggested stating on the website that CPHS acts in that capacity as a privacy board.

Dr. Dinis emphasizes that under federal regulations, PII is regarded as human subject contact. She noted that secondary data containing identifiable information is considered human contact research. Attorney Goldman observed that departments are advocating for a 'belt and suspenders' approach and agreed with Dr. Dinis that most cases will involve human subjects, thus necessitating an IRB approval for the research project.

No comments were made by the public.

Motion: Ms. Kurtural moved, and Dr. Ventura seconded the motion in stating the responsibilities of CPHS we include that CPHS may act as a privacy board when the context requires for the approval of HIPAA waiver authorizations and state this on the CPHS website.

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

Total= 11 In Favor- 9, Opposed- 0, Abstained- 2

E. Overview of regulations process

a) Presentation of the progress to pass new regulations

Dr. Dickey indicated that the upcoming discussion would center on the regulation process. Dr. Dickey noted that Attorney Goldman's presentation would be pertinent to any regulations that CPHS might consider altering within the IPA. Dr. Delgado advised that the CPHS should understand two contexts regarding the regulatory process as it pertains to them, especially concerning potential proposed regulations related to the IPA. Dr. Delgado mentioned that this process would also apply if CPHS opts to impose fees on researchers from outside the

California Health and Human Services (CalHHS) for the CPHS board's review services. Dr. Delgado introduced Attorney Goldman who will provide an outline of the regulatory process.

Attorney Goldman clarified that a regulation is a standard of the general application, that applies to a group of people. A regulation is a procedure that implements, interprets, or makes a specific law. In this situation pertaining to CPHS, the regulation would make a specific law that authorizes this body to approve IPA releases. Attorney Goldman explained once a state agency decides to conduct a rulemaking action, it engages in preliminary and informal rulemaking activities where the agency gathers materials and information necessary to develop the documents required to conduct a formal rulemaking proceeding. During part of the process, the rulemaking agency has discretion whether to include the public during this stage of the rulemaking process.

Attorney Goldman clarified that in order to initiate a formal rulemaking action, an agency publishes a notice of proposed action in the California Regulatory Notice Register. The agency must also mail the notice of proposed action to those people who have requested notice of regulatory actions and post the notice and accompanying materials on the agency website. After publishing the notice in the register, the agency has one year to complete the rulemaking process and submit the completed rulemaking file to the Office of Administrative Law (OAL).

Attorney Goldman explained that documents needed for a rulemaking package are the text of the proposed regulation. A notice of proposed action (NOPA), which is what CPHS would put in the State Registrar and be stated on the CPHS website. The NOPA contains a variety of information about the nature of the proposed regulatory changes (e.g., statutory authority and the laws being implemented), and contains procedural information (e.g., deadlines for submitting comments and scheduling hearings). It gives the public a timeframe and the manner the public can comment on the proposed regulation. The Initial Statement of Reasons (ISR) would be included in the rulemaking package. The ISR document explains the reasons why the agency is making the proposed regulatory changes. Lastly, the Economic Fiscal Impact (EFI) would be included in the rulemaking package. The EFI includes information on the estimated private and governmental monetary impacts of the proposed regulations. There is a document which puts forward the economic and fiscal impact of the regulation. CPHS would have to identify the cost of the regulation, both on the State government side and also on the side of business, or healthcare community, or the subjects of the legislation.

Dr. Delgado asks attorney Goldman where the line is drawn regarding when a regulation needs to be proposed, and when it does not. For an example, earlier the committee made a motion regarding CPHS actings as a privacy board. Dr. Delgado asked Attorney Goldman why regulations are necessary for charging fees, or potential amendments to the IPA decision, while other motions do not need to go through the regulatory process. Attorney Goldman explained that regulations apply when there is a granting or deprivation of a right or privilege. In the case of charging fees, if CPHS were to impose fees, that action would need to be authorized through regulations. If CPHS is interpreting a statute that either grants or denies approval of the right to research, best practices would be to pass the regulations though rulemaking. If CPHS chose not to, it would run the risk of the principal CPHS policy being challenged as an underground regulation. Attorney Goldman explained that policies and procedures govern internal processes, so generally, regulations are not needed for changes to the policy and procedure handbook unless they have a significant public impact. Dr. Bazzano asked for clarification on how this would pertain to CPHS relating to the IPA. Attorney Goldman advised the committee to recall the list of criteria under the IPA that CPHS uses to review the release of information. There is an enumerated set of criteria and CPHS's interpretation of the IPA is that the list of criteria is non-

exclusive. Theoretically, additional criteria could be added by CPHS. If CPHS added new criteria outside of what's expressly stated in the IPA, that kind of implementation or implementation of the statue, would require adoption through a regulation.

Attorney Goldman explained that if CPHS were to issue a policy that all projects that came in front of CPHS, were subject to some additional criteria, that would require a regulation, but if CPHS were to decide to extend new criteria under the IPA on an ad hoc bases, that approach would not require regulations but poses additional risks to CPHS.

Attorney Goldman explained that once all the documents are sent out and have posted the notice of the regulation on the agency website, the public has a minimum of a 45- day period to comment to the agency in writing on the proposed regulation. In addition, a rulemaking agency has the option whether to hold a public hearing on a proposed rulemaking action. If the public requests a hearing, then the agency must provide a hearing for the public. In the case of holding a hearing, comments can be provided at the meeting both verbally and remote.

Attorney Goldman explained that the response to public comments, the rulemaking agency must summarize and respond to timely comments that are directed at the proposal or at the procedures followed by the agency during the rulemaking action. For each comment, the agency must include either an explanation of how the proposed action has been changed to accommodate the comment or state the reasons for rejecting the comment. The summary and response to comments are included as part of the rulemaking file in a document called a Final Statement of Reasons (FSR).

After receiving the public comment period, a rulemaking agency often decides to change its initial proposal either in response to public comments or on its own. Non-substantial changes (those that do not alter the regulatory effect of the proposed revisions) do not require further public notice. If any substantial changes (those that alter the meaning of the regulatory provisions) are made, further public notice is required, and the public has the opportunity to comment.

The last step in the rulemaking process is to submit the final rulemaking package to the Office of Administrative Law (OAL) for review. A rulemaking agency must transmit a rulemaking action to OAL for review within one year from the date that the notice was published in the California Regulatory Notice Register (CRNR). Once submitted, OAL has 30 working days to conduct a review of the rulemaking record to ensure that the agency satisfied the requirements of the APA and OAL's regulations. OAL will then either approve the rulemaking action and file the proposed regulations with the Secretary of State or disapprove the rule making action.

Ms. Lund asked Attorney Goldman for clarification on who would be the responsible party for the rulemaking process. Ms. Lund pointed out that Center for data Insights and Innovation (CDII) would be responsible for the regulations with the committee's input. Attorney Goldman clarified the regulations would be issued in partnership with CDII. The statue that creates this body is placed within the division of law relating to CDI. While CPHS is afforded independent decision-making authority, CPHS is housed within CDII. It's CDII that has the authority to issue regulations, and CPHS would be working in partnership with CDII and their staff, to promote these regulations. Attorney Goldman pointed out that developing a regulation package is extremely labor intensive that a regulation package typically can take over a year from the idea phase to when the regulation is passed.

No public comments were made.

F. Common Rule and Information Practices Act (IPA)

a) Discussion of options for committee action

Dr. Dickey requested Attorney Goldman to review the memo with the committee. Attorney Goldman provided a quick recap to the committee regarding the Common Rule and IPA reviews. The Common Rule review is for research with CalHHS engagement, while the IPA review is engaged in disclosures to entities outside of state, where CalHHS is not engaged in the research. The IPA has a list of criteria for the disclosure of information. Attorney Goldman explains that, in their opinion, the list is non-exclusive, meaning CPHS could, if it chooses to use additional criteria as part of its decision-making process for the disclosure of PII. However, that decision is constrained by the purpose of the IPA. CPHS could not impose criteria outside the general purpose of the IPA, which is protecting individuals' privacy and security.

Attorney Goldman explained two different approaches to add criteria to the IPA. The first approach would be to apply the criteria on an ad hoc basis without regulation and without adding it to the policy and procedure manual. This approach comes with the risk of inconsistent application of additional criteria and the possibility of researchers claiming the additional criteria were applied arbitrarily or discriminatorily. The other approach would be to create standards of general application for when and how to apply additional criteria through regulations. The next step would be to apply a basic policy framework and come up with a set of principles or ideas that would be turned into the regulatory language.

Ms. Lund inquired with Attorney Goldman about the extent of additional criteria that might be included in the IPA. She questioned whether criteria concerning the ethics of the research and those included in the Common Rule could be incorporated into the IPA. Attorney Goldman clarified that only criteria pertaining to the protection of individual privacy and security may be incorporated into the regulations for implementation or interpretation.

Dr. Schaeuble inquired about the committee's ability to incorporate statements or examples into its policy and procedures to address additional privacy considerations on an ad hoc basis. Attorney Goldman recommended a thorough examination of the proposed statements and suggested that while this could be a viable method, it would require further scrutiny. He also cautioned that introducing criteria ad hoc could lead to allegations of arbitrary or discriminatory practices. Dr. Schaeuble proposed evaluating all options to determine if any could be less burdensome than the regulatory process.
Dr. Dinis requested contact details to propose amendments to the IPA, observing that it is antiquated and does not account for recent technological developments and the utilization of secondary data in identifying research participants. Attorney Goldman pointed out that such amendments are within the purview of the legislature, and individuals are free to collaborate with their local representatives on these matters.

Ms. Kurtural recommended navigating the regulatory process because the IPA's guidelines on assessing minimal risk for projects are vague. She emphasized that this approach offers more control compared to directly approaching the legislature. Furthermore, Ms. Kurtural proposes that the CPHS could introduce a two-tier system via regulations, which would specify criteria that must be met when merging certain data with other datasets.

Dr. Schaeuble recommended that the committee develop a preliminary list of scenarios and criteria for IPA reviews. He proposes exploring both regulatory implementation and the

feasibility of a safe alternative to integrate into the policies and procedures. Attorney Goldman advised compiling a set of additional criteria for the committee's consideration and reviewing them to ensure the regulations are logical.

Dr. Dickey requested that members submit a list of criteria to the CPHS administrator, Agnieszka Rykaczewska, to be discussed at the August meeting.

Dr. Schaeuble asked the committee if they were in consensus that there are situations where the limited criteria in the IPA are insufficient for the review process, and therefore CPHS should explore the regulatory process. Dr. Dickey acknowledged that multiple committee members were not satisfied and needed to investigate further to outline the additional criteria.

Ms. Kurtural suggested looking at the past 24 months and reviewing the specific used cases related to data-only projects the committee has reviewed that raised concerns about, to categorize the different type of data-only requests.

Ms. Lund noted to the committee that IPA reviews are usually expedited. She emphasized that many projects are not presented to the entire committee unless the reviewers deem it necessary. Ms. Lund proposed that the categorization should not be between data-only and human subject projects, but rather between IPA projects and Common Rule projects. She explained that a data-only project undergoes a Common Rule review if it involves the CalHHS agency in any capacity, whether through funding, contracting researchers, engaging universities, providing staff support, or involving subjects in state custodial care. Ms. Lund noted that secondary data containing PII would require a Common Rule review, even if there is no human subject contact. Attorney Goldman agreed with Ms. Lund's suggestion of categorizing the projects under IPA and Common Rule review.

Dr. Dickey summarized the discussion, emphasizing the next step of submitting specific case examples from the past to the CPHS Administrator in advance of the next committee meeting. Dr. Schaeuble recommended that committee members provide examples that may exceed the minimum IPA requirements, along with any additional criteria that should be considered in those particular instances.

Motion: Dr. Schaeuble moved, and Dr. Johnson seconded the motion that the committee acknowledges that the criteria stated in the IPA may not provide sufficient protection for data privacy and security in some instances and is investigating situations where other criteria might be considered.

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

Total= 11 In Favor- 11, Opposed- 0, Abstained- 0

G. Proposed revisions to CPHS voting policies: Clarifying reasons for abstentions and objections.

a) Review of proposed revisions to CPHS voting policies

Dr. Dickey addressed the committee regarding the existing voting policies and procedures, highlighting that the current policy and procedure mandate members who vote "no" to provide their reasons for opposition. Dr. Schaeuble presented his proposed amendments to the voting policies, referencing the document he had submitted before the meeting. Dr. Schaeuble pointed out the necessity for new wording, stemming from a previous meeting where a member was asked to state the reason for their vote. Dr. Schaeuble noted that requiring members to justify the way they have voted is not consistent with other voting scenarios. Dr. Schaeuble rephrased the language to state that members are encouraged to express their reason(s). The most recent language assumes that the decision of the committee would to be to approve, and the votes in the minority are encouraged to express their opinions. Dr. Schaeuble provided new language under the meeting minute section on page 17 of the policy and procedure. The new language states that the meeting minutes should include reasons for minority votes if they have been stated. Dr. Schaeuble noted that this is not a big issue since the meeting minutes already reflect the discussion during the meeting and members who vote on the minority will likely state their reasons during the discussion.

Dr. Delgado thanked Dr. Schaeuble for proposing the new language and presenting it to the committee. Dr. Delgado expressed her support for the new language.

Dr. Dickey commented that CPHS should provide researchers with the reasons for turning down their project, as researchers would need to know that information to revise their project to accommodate the committee's concerns. Ms. Lund provided clarification to Dr. Dickey that if there are minority votes, the project has received a majority vote to approve or not approve. The reasons for minority votes are not feedback for the researcher. Dr. Delgado agreed that members who vote in the minority do not influence whether a project is approved or not. Since the minority votes have no impact on the approval of a project, the minority votes should not have to provide justification. Ms. Lund expressed her support for the new language provided by Dr. Schaeuble and noted that the current language included in the policy and procedures is not fair to reviewers if they are forced to give a reason if they choose not to.

No public comment was made.

Motion: Dr. Schaeuble moved, and Dr. Dinis seconded the motion to approve the proposed revisions in the proceeding section of the policies and procedures manual on page 19, to say "Approval of a motion requires votes in favor by a majority of CPHS members present in-person or remotely, excluding the Chair. The Chair may only cast a vote to break a tie or if needed to establish a quorum for the meeting. Motions receiving a tie vote do not pass. Members whose votes are in a minority are encouraged to express their reason(s)."

Move to amend the meeting minutes section of the policies and procedures manual on page 31 to say, "Motions and the decision of CPHS, including votes in favor, votes opposed, abstentions, and members absent at the time of the vote (e.g., Total= 13; In Favor- 12, Opposed- 1, Abstained- 0), as well as reasons for minority votes, if they have been stated."

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

Absent: Dr. Hess
Not Recorded/ Technical Issue: Dr. Bazzano

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

H. Process for project recategorization from research to public health surveillance

Dr. Dickey provided context on the 2018 amendment to the Common Rule which reclassified public health surveillance projects as exempt. He noted that CPHS has projects from before 2018 that could be re-categorized as public health surveillance. The Common Rule states the criteria for projects to meet the exemption but does not require that projects meeting those criteria from before 2018 must be re-categorized as public health surveillance. Dr. Dickey explained that the internal process to reclassify a project under public health surveillance needs to be done in conjunction with the chair or vice chair.

Ms. Lund asked for clarification on why that decision was made, and the justification behind the decision. Dr. Dickey noted that it would be more efficient to have the primary reviewer, along with the chair or vice chair, make that decision rather than bringing the projects to the full board. Ms. Lund expressed her concerns about long-term projects approved in the 1990s and early 2000s that have returned to CPHS for amendments and are no longer considered research. She voiced concerns that state agencies might be using CPHS as a workaround since agencies are limited on what they can do with routine work and public health surveillance unless they get an exemption. Ms. Lund objected to providing exemptions that allow government agencies to work around the rules and felt strongly that long-term projects fitting the new criteria for public health surveillance should be reclassified as such by CPHS.

Dr. Delgado asked if the committee had any amendments they would like to propose to what Dr. Dickey was suggesting for the process of reclassifying public health surveillance projects. Ms. Lund suggested that the projects come before the full board for a review, rather than an executive decision made by the chair or vice chair. Dr. Dinis agreed with Ms. Lund that the projects should go to the full board for review. Dr. Dinis commented that it's not consistent with other policies and procedures for the chair or vice chair make an executive decision without full board review. Dr. Dickey suggested that if a reviewer disagrees with the chair or vice chair, they have the right to bring it to the full committee. Dr. Dickey suggested amending the language to state that any decisions should be made in consultation with the chair or vice chair but brought to the full committee if there is disagreement.

Dr. Delgado suggested finding a way to memorialize the agreement since no motion was needed. Agnieszka Rykaczewska, CPHS Administrator, recommended having a motion and incorporate it into the policies and procedures.

No Public comment was made.

Motion: Dr. Dickey moved, and Dr. Johnson seconded the motion for projects that need to be reclassified as public health surveillance, the reviewer should consult with the Chair or Vice Chair. If there is a disagreement the project will be presented to the full committee for review.

Approve: Dr. Dickey, Dr. Johnson Dr. Ruiz, Dr. Dinis, Ms. Kurtural, Ms. Lund, Dr. Azizian, Dr. Ventura, Dr. Schaeuble

Oppose: None.
Abstain: None.
Absent: Dr. Hess
Not Recorded/ Technical Issue: Dr. Bazzano, Dr. Palacio

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

I. Public Comments

None.

J. Next Meeting

The next CPHS meeting is scheduled to be held on Friday, August 2, 2024.

K. Adjournment

This meeting was adjourned at 11:52 AM on July 12, 2024.