

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



GAVIN NEWSOM
Governor

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

Meeting of the Subcommittee on Drafting Recommendations for Regulations

Friday, January 10th, 2025
8:30 a.m.

Subcommittee Members

Maria Dinis, PhD, MSW
Carrie Kurtural, JD
Laura Lund, MA
John Schaeuble, PhD, MS

Remote Attendees

Maria Dinis, PhD, MSW

Zoom:

[CPHS January 10, 2025,
Full Committee Meeting](#)

CPHS Administrator
Agnieszka Rykaczewska

Meeting ID: 161 774 1845
Passcode: 533623

Location:

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Meeting ID: 161 774 1845

MINUTES

Committee Members Present in Person:

Laura Lund, MA
Carrie Kurtural, JD
John Schaeuble, PhD, MS

Committee Members Present Remotely:

Maria Dinis, PhD, MSW

CPHS Staff Present in Person:

Agnieszka Rykaczewska, PhD
Sussan Atifeh
Karima Muhammad

CPHS Staff Present Remotely via ZoomGov:

Nicholas Zadrozna

Also, Present (All via ZoomGov) Members from the Public:

Evan White

A. Welcome

Ms. Lund kindly reminded Dr. Dinis to keep the camera on during the entire meeting due to Bagley-keen requirements since she is attending remotely. Sussan Atifeh established quorum by roll call.

B. Discuss Potential Revisions to Framework

a) Review motion made by the Committee for the Protection of Human Subjects (CPHS) at the December meeting.

Ms. Lund thanked Dr. Schaeuble for all his work on the revisions and for the supporting material he provided. Ms. Lund asked Dr. Schaeuble to further explain the supporting documents, and what is in the framework.

b) Review latest drafts of framework and discuss any further potential revisions or next steps.

Dr. Schaeuble noted he made changes in three different places on the suggested framework document. No changes were made on the first page of the document. On the second page in response to what was discussed at the last full committee meeting, an additional item was added to the middle section of the document:

Researchers plan to use technology such as artificial intelligence and machine learning that may increase the risk of individuals being reidentified.

Dr. Schaeuble advised his word choice for the new section was based on research literature and protocols CPHS has reviewed. Dr. Schaeuble advised generative Artificial intelligence (AI) is too specific since the technology changes so rapidly. He noted the phrase 'artificial intelligence' would be more relevant and have lasting power.

The words 'machine learning' were added as it is a common phrase found in research literature dealing with this topic and it has appeared in several protocols used by researchers, including machine learning techniques in data analysis. Dr. Schaeuble asked for feedback on the phrasing of this item. Dr. Schaeuble expressed that Attorney Goldman was satisfied and did not suggest making any changes to the wording.

Ms. Kurtural thanked Dr. Schaeuble for proposing the new language and advised the phrasing makes sense. Ms. Kurtural suggested when the regulations are being written to check back in with Attorney Goldman to see if the State of California has already created a universal definition for 'artificial intelligence' and 'machine learning'. Dr. Schaeuble agreed and advised it is difficult to determine what the next technology will be.

Ms. Lund suggested that the new phrasing is great and Dr. Schaeuble captured what the committee members were concerned about. She responded to Ms. Kurtural's comment, advising that Attorney Goldman will draft the regulation and check for definitions and alignment with what California already has in place. Dr. Dinis agreed with the phrasing as the possibility to reidentify test subjects through artificial intelligence is high and expressed that she is happy that the new phrase was included.

Dr. Rykaczewska asked a clarifying question, advising the regulation is not saying the phrases 'artificial intelligence' and 'machine learning' cannot be used, but rather requires an explanation of the risks associated with reidentification and the measures taken to mitigate those risks. Dr. Schaeuble agreed and emphasized assessing the extent to which the possibility of reidentification is increased as a risk, and how the risk is being handled.

Ms. Lund reminded members of the public that second part to which the bullet point was added describes the risks CPHS is concerned about that should be paid specific attention to in IPA reviews. It is a risk but is not something that would disallow the protocol from being approved. Dr. Schaeuble emphasized that is true for all the items listed in the middle section.

Dr. Schaeuble advised the second change is in the first sentence of the third part of the document:

Applications to CPHS for an IPA review shall include the following information when any of the risks enumerated above are applicable in the research.

This is a clarification to follow up on the full committee's decision at the last meeting that CPHS does want to have additional information when any of the risks in the middle section are something that applies in the research. The subcommittee advised there were no concerns.

Dr. Schaeuble advised the third change is in the first item in the section following the third part of the document:

To the extent that it is available for the data sources to be used in the study, what information was given to individuals when their data was collected, about the possible use of that data in research.

To make it clear that CPHS is asking for information, knowing it might or might not always be available, but to the extent that it is.

Dr. Schaeuble also noted a phrase which he put in brackets and flagged as optional:
From a Notice of Privacy Practices or other communication about privacy.

Dr. Schaeuble noted that Attorney Goldman suggested that the phrase may not be necessary and the first part of the sentence asking what information was given to individuals, is likely enough. Dr. Schaeuble initially thought to leave it out but brought it to the subcommittee attention to see if they want taking the phrase out or leaving it in.

Ms. Kurtural advised her observation is two-fold. It's helpful to be direct with the applicants and what CPHS is asking for. CPHS is looking for any source of communication about privacy rights or Notice of Privacy Practices (NPP) and that does not necessarily have to be in the regulation itself, as Attorney Goldman advised. Upon CPHS revision, the application form can include it as a question in an additional portion of the application.

Dr. Dinis agreed that it was not necessary to include it in the regulation and it is good to provide examples because sometimes researchers ask for examples. Ms. Lund agreed with all comments, advising additional information. CPHS already provides examples to researchers in the protocols, which is the appropriate place to do so, as CPHS may want to highlight them as examples and rather than just as NPPs. The subcommittee agreed there is no need to include it in the regulations.

Dr. Schaeuble advised of two alternative options to finish the sentence:

...the context or situation in which that information was provided. or;

...the context or situation and how that information was provided.

Dr. Schaeuble advised that the first alternative option is closer to what CPHS would ideally like to see, even if difficult to achieve in practice. CPHS should want to know, regarding the use of information being provided to subjects, the likelihood of subjects seeing the privacy information, if they did see it, knowing how much other information subjects were burdened with at the same time, and whether the subjects were in a situation where they could think about and understand the information being given to them or if they were in a stressful circumstance where they could not understand. Can researchers obtain from agencies providing data a couple of sentences saying, for example:

Typically, the data were obtained under the following circumstances:

Dr. Schaeuble advised this would go a long way towards giving CPHS understanding of the way privacy information was provided to people. He noted he is not sure how willing or able agencies would be to include such language and hoping it is something CPHS can work towards establishing. The second alternative option is a shorter or more direct approach which focuses on how the information was provided. The concern in phrasing is the question leads to responses like:

'There was a weblink subjects could go to for privacy information.' OR 'Privacy information was among various documents that were provided to people.'

Dr. Schaeuble prefers the first alternative, but Attorney Goldman, however, preferred the more simplified wording of the second alternative option. Dr. Schaeuble opens the floor to the other members to discuss this topic.

Ms. Lund responded to Dr. Schaeuble, noting she understands why he would want that information as a reviewer. However, regarding the regulations, Ms. Lund suggests CPHS should be specific regarding what is being requested that burden researchers and state agencies. Justifying that the information being requested is information CPHS would use in deciding on protocol. When reading the Information Practices Act (IPA) and understanding what CPHS can consider in an IPA review, key concerns include whether a privacy notice existed and whether the agency collecting the data had a mechanism to ensure subjects received it. That satisfies the entire legal obligation of the researchers or agencies. These are data collected for non-research purposes, collected for state agencies to perform some state agency function, then incidentally, later used for research purposes because it is data that is already captured. When there are conversations about subject data, research is the last thing on everyone's mind, including state agencies, researchers, service providers, and subjects. When CPHS is considering IPA projects, CPHS cannot consider whether subjects were informed as that information is outside the scope of what CPHS can consider. Ms. Lund advised it is burdensome to ask this of researchers and it is not possible for CPHS to get satisfactory answers to all the questions enumerated in the regulation draft. It is important to understand from a research perspective why CPHS would want to know if the subjects had the opportunity to see the privacy information and under what circumstances. CPHS cannot decline a protocol under the IPA if CPHS is not satisfied with how subjects received information about how their data would be used in research. Ms. Lund concluded there is no point in CPHS requesting this information if it is not relevant to the IPA review. Ms. Lund advised leaving both options of the regulations and stick with the following language:

To the extent it is available for the data sources to use and study what information is given to individuals when the data is collected about the possible use of that data in research.

Ms. Kurtural advised legal requirements already exist. HIPAA covered entities must follow federal law in how they deliver the Notice of Privacy Practices, including rights and practices which typically mention research. There is a signed acknowledgement when subjects receive services. Other documents like the Notice of Privacy Rights may contain similar information regarding the practices any department can use. This is outside of CPHS jurisdiction, and CPHS can put their trust in the departments delivering this information because they are required to do so by law. A signed acknowledgement is required by law for departments under HIPAA.

Ms. Lund agreed with Ms. Kurtural about the HIPAA databases and advised for non-HIPAA databases, there is no signed acknowledgement. Ms. Kurtural emphasized CPHS's trust must be placed in the departments that are meeting the requirements under the law, as all departments are subject to privacy and confidentiality laws.

Dr. Dinis advised focusing on context or situation and how the information was provided. This would give the researchers options to describe how the information was provided to them.

Ms. Lund responded to Dr. Dinis suggesting this would be burdensome for the departments. A lot of the CDPH databases are established within different clinics and hospitals. They will have different procedures, and if what they are doing complies with state laws, they can do it different ways. Ms. Lund noted she understands why CPHS would want to capture this information, however, it is burdensome for the researchers because they would try to capture the information in the way CPHS would prefer to receive it.

Ms. Lund recommended not implementing item two or three and advised that was up for group discussion. Ms. Lund suggests the researchers will not be able to answer how.

Ms. Lund advised the other types of administrative datasets collected are hospital based, but they do not fall under HIPAA regulations, as it is entirely different. Every hospital can have a different way of delivering privacy information. Information is delivered in-person or electronically. Death data is mortuary-based; some are corporate, and some are small and may have different procedures in place.

Ms. Lund expressed that CPHS is not looking to change or impose anything on state agencies. CPHS does not have the authority or purview to regulate state agencies that are already regulated by state law. Ms. Kurtural also advised of the risk of challenges and legal ramifications.

The discussion concluded with an agreement to end the item right before the first set of brackets.

Ms. Lund concluded the discussion by summarizing that the CPHS sub-committee is satisfied with the language for the additional risks regarding artificial intelligence and machine learning and does not have suggestions for changes or revisions to that language. The introduction to part three remains the same with no suggestions for changes. The first item prior to the first bracket is agreed on, and based on the discussion, CPHS will not include the language from any of the three additional brackets. The subcommittee agreed with the conclusion provided by Ms. Lund.

Ms. Lund opened the discussion up for the public to provide comments.

Dr. Evan White, Executive Director of the CA Policy Lab, used to be a regulatory attorney for the federal government working at the Consumer Financial Protection Bureau specifically working on consumer privacy regulations. Dr. White reiterated that he objects to these IPA regulations in their entirety. These IPA regulations fall outside the authority under the IPA and wrongheadedly assume CPHS will substitute personal opinions for the considered judgements of the legislature and the IRBs already reviewing these projects. Regarding the artificial intelligence addition, it is not clear to Dr. White that CPHS has sufficient expertise on artificial intelligence or machine learning to know exactly what's being added with this language. For example, all regressions are machine learning and most research projects CPHS reviews involve some sort of regressions in them. It's not clear to Dr. White that CPHS wants all this information in the applications. The terminology used here is so broad that it includes things done naturally in research projects as part of programming algorithms and it is not clear CPHS has the expertise to find the right language. The understanding of 'reidentification' exhibited by CPHS is startling to Dr. White. Artificial intelligence is not the threat to reidentification. Beyond the research identified in the 2 articles circulated by Dr. Schaeuble, the baseline risks for re-identification are already very high for any data that's personable, even if 'de-identified'. The overall risk is low because of the context in which the data is given out, which is to a trusted researcher who has demonstrated that they have the requisite data security requirements in place. It's not that the data can't be reidentified, as most of the data sets given out are re-identifiable based on the amount of personal information that already exists on the internet. Reidentification is possible without any machine learning algorithms.

Dr. White shared CPHS's concern about reidentification and think CPHS is going about this the wrong way. CPHS should pause and consider why there is focus on reidentification when the IPA is only talking about identified data, which is information that can be linked back to an individual. CPHS is importing a framework from the IRB that doesn't apply in the context of the IPA. On the Notice of Privacy Practices provision, Dr. White wholeheartedly agreed with Ms. Lund: Why ask for it when you can't legally use it? Dr. White suggested that the committee has thrown on the brakes a little too late and is unsure whether any of this can be used legally under the IPA. The IPA does not allow for any of these regulations. Departments are the experts in their own laws and whether the data should be released. In what context can CPHS use the Notice of Privacy Practices? Essentially, CPHS would get the Notice of Privacy Practices, and would be saying the data can't legally be released because of what's in the notice. It's the agency that owns that data who makes the determination. It's not clear to Dr. White that CPHS is able to use the information legally. Dr. White concluded his comments, advising that just because he disagrees does not mean he does not respect what CPHS is trying to do, and he hopes that CPHS takes his words into account.

No other public comments were provided.

Ms. Lund thanked Dr. Schaeuble for the additional two articles, noting that they were interesting and eye-opening. She suggested that the articles reinforced her belief that CPHS's work on the IPA and its efforts to ensure sufficient protections serve as CPHS's guiding principle when conducting IPA reviews.

Dr. Schaeuble advised it's disturbing to see how easily re-identification can be possible. He noted that CPHS sees this concern in two situations. The first situation is where researchers obtain personally identifiable data and tell CPHS they are removing identifiers and proceeding to analyze the data set that has identifiers removed. The second situation is where researchers receive data where the identifiers have been removed before they receive the data. Dr. Schaeuble expressed that after reading the articles, it is disturbing that the concept of deidentified data in either of those situations does not exist anymore in this world. Past assertions from researchers that the identifiers are gone, and therefore subjects cannot be identified, is no longer an accurate statement.

Ms. Lund followed up on Dr. White's comment about when the IPA applies. She noted that the IPA applies when State agencies are releasing personally identifiable information. CPHS is focused on re-identification because the number one risk mitigation strategy when they submit protocols for IPA review, is that data will be de-identified. CPHS is examining the effectiveness of de-identification as a safeguard across different types of datasets. Especially in merged data sets and data sets that may have other kinds of variables in them that could be used in conjunctions to identify individuals. Ms. Lund wants to make it clear that's why CPHS is focused on the identification. It's not that the data are already de-identified when received from state agencies; rather, de-identification is being proposed to CPHS as a risk mitigation strategy.

Ms. Kurtural expressed concern about re-identification on anything that is published that might be at the individual level.

Dr. Dinis agrees with the other members that the concern is that people can be re-identified and suggested that the law was written at a time when they were not able to, but things have changed with the advancement in technology.

Ms. Lund opened the discussion up for public comments. No public comments were provided.

Motion: It was moved by Dr. Schaeuble and seconded by Ms. Lund that the CPHS Subcommittee forwarding to the CPHS Full Committee, a 9th draft of the suggested framework in which the bracketed phrases from the 8th draft have been removed.

Approve: Dr. Schaeuble, Ms. Lund, Dr. Dinis, Ms. Kurtural

Oppose: None

Abstain: None

Absent: None

Total= 4

In Favor-4, Opposed-0, Absitained-0

C. Next Meeting

The CPHS sub-committee will wait to hear the decision of the Full Committee to determine whether there is a need for a subsequent meeting of the subcommittee and, if so, determine the date and time.

D. Adjournment

This meeting was adjourned at 9:30 A.M on January 10, 2025.