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, September 13, 2024
9:00 AM

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

Remote Attendees
Maria Dinis, PhD, MSW

Zoom:
CPHS September 13, 2024, Sub-Committee Meeting

Meeting ID:161 257 5581
Passcode: 613827

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

Phone:
+1 669 254 5252 US (San Jose)
+1 669 216 1590 US (San Jose)
+1 646 828 7666 US (New York)

Meeting ID:161 257 5581

CPHS Administrator
Agnieszka Rykaczewska, PhD.

Committee Members Present in Person:

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

Committee Members Present Remotely:

Maria Dinis, PhD, MSW

CPHS Staff Present in Person:

Agnieszka Rykaczewska, PhD
Karima Muhammad
Nicholas Zadrozna

CPHS Staff Present Remotely:

Sussan Atifeh

California Health and Human Services Staff Present in Person:

Jared Goldman, General Counsel
Maggie Schuster, Attorney

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

Agnes Balla
Jennifer Ahern
Regan Foust
Evan White

A. Welcome

Laura Lund called the sub-committee meeting to order. The purpose of the CPHS subcommittee is examining language used in drafting regulations to support the work CPHS performs in reviewing research projects. The sub-committee quorum was confirmed, and members of the public were requested to introduce themselves. The meeting was attended by the following public members virtually:

Agnes Balla – University of California, Office of the President – Research Policy Office
Jennifer Ahern – Professor/Associate Dean of Research/Regional Associate Dean, School of Public Health – University of California, Berkely
Regan Foust – Executive Director – Children's Data Network – University of Southern California
Evan White – Executive Director – California Policy Lab – University of California

B. Revision Reviews

The CPHS Subcommittee members were called to begin discussions. The discussion materials included a proposed framework document created by Dr. Schaeuble. These materials had been emailed to the committee members before the meeting and were also accessible on the CPHS website.

Dr. Schaeuble presented a summary of his revised framework document, now in its fifth draft due to modifications in language. The language revisions in this draft were confined to the second page, leaving the first page unchanged. He requested the subcommittee's feedback on the alterations made to the final section of page two, which pertains to the actions a committee member might need to take when faced with the types of risks mentioned earlier in the document.

The first item in that section states, “The Researchers investigated what the individuals whose information will be used were told, when the data were originally collected, about using their information for research, and whether that was sufficient to serve as an informed consent”. The second item states, “The proposed use of data does not exceed any authorization given, at the time the data were originally collected, by the individuals whose information will be used, or would be eligible for a waiver of informed consent”. Dr. Schaeuble sought comments on the last two items from the subcommittee, highlighting that the final item mentions, "The researcher avoids collecting particularly sensitive identifiers or information that is not necessary for conducting the research."

Dr. Schaeuble requested Attorney Goldman's opinion on whether the section discussing the exclusion of unnecessary variables might be addressed by existing language in the Information Practices Act (IPA). He mentioned that he included this item because it complements the third item and expressed willingness to remove them from the document if they are already encompassed by the IPA.

Ms. Lund inquired if all subcommittee members concur with Dr. Schaeuble's proposal to discuss the section first and then refer back to the document's initial section, or if there are any alternative suggestions for proceeding. While Ms. Lund agreed with Dr. Schaeuble's approach, she invited further input from the other subcommittee members.

Ms. Kurtural highlighted to the subcommittee members that the second point in the informed consent section already has a factor analysis for HIPAA-covered departments regarding the acceptance of a HIPAA waiver of informed consent. This analysis applies to HIPAA-covered departments under CalHHS, including parts of the California Department of Public Health (CDPH), Department of Health Care Services (DHCS), Department of Developmental Services (DDS), among others, but not necessarily to all departments, such as the California Department of Social Services (CDSS).
Ms. Kurtural recommended examining the HIPAA factors to achieve the subcommittee's objectives and determine necessary changes to the regulatory framework. She concurred with the language concerning the totality of the circumstances and suggested a base framework for what CPHS should consider. She mentioned that CPHS can then assess changes to the regulatory framework by referencing federal law, thus avoiding the need to start from scratch.

Ms. Lund sought clarification on the CPHS's focus on drafting regulations to clarify CPHS authority under the IPA. She mentioned that many of CPHS's concerns fall outside the Common Rule, as they are reviewed under the IPA, and not as an IRB—the aim of the proposed regulations is to better comprehend the criteria applicable for IPA review and to establish a framework for these criteria.

Ms. Lund mentioned her discomfort with the idea of mandating informed consent for extensive state databases. She explained that while departments collecting medical data must adhere to HIPAA standards and ensure individuals are fully informed of their rights under HIPAA, many large state databases used for research lack any form of informed consent and in some instances, laws even prohibit it. For example, birth certificate data, which includes personal and medical information about the parents and child, is not subject to HIPAA by state law. This data is compulsory at the time of collection for birth registration. Legally, state agencies must disclose the intended use of collected data, but individuals cannot give consent or opt out, as is the case with the California Cancer Registry (CCR). Ms. Lund pointed out that it is impractical to expect researchers to implement an informed consent process for these large databases, suggesting a need to revise this requirement due to its impracticality.

Dr. Schaeuble referred to the beginning of the first item in the last section regarding researchers' investigation about what people were told, and how they were told when the data were originally collected. The second part of the sentence is whether that was sufficient to serve as an informed consent. In the situation Ms. Lund highlighted reviewers need to understand that people may have been informed about possible use of their data where context does not give them the option of consent. Reviewers should be assessing the risk, which need to be evaluated in context of a situation where they are not permitted to provide consent. The question arises whether the use of specific variables introduces a greater risk to individuals. Dr. Schaeuble clarified that his intention was to create ~~this with the~~ language that not every situation should be able to show informed consent, but to discover whether there was consent at all, or if it is even possible.

Ms. Kurtural observed that CPHS handles the data from CalHHS and its departments. It was mentioned earlier in the meeting that many departments already possess a Notice of Privacy Practices. Ms. Kurtural expressed concern about researchers wanting to combine state data with datasets from external entities. CPHS and CalHHS would be unaware if these entities have secured informed consent for their data collection. She proposed that CPHS should not increase the researchers' burden to obtain a privacy notice from CalHHS departments, as CPHS already has access to these notices. Instead, she recommended providing this information when researchers seek to link with datasets outside to CalHHS.

Dr. Schaeuble pointed out that researchers often request various state data sources and seek to link them with data from outside CalHHS. From a practical standpoint, ~~it~~ is it practical whether CPHS can obtain privacy practices for external entities or ~~if~~should it ~~should~~ rely on researchers to investigate these practices themselves. Legally, the extent to which CPHS can inquire about external data sources remains unclear. If limitations exist, CPHS may find itself without information on these external data sources, and legally, it may not be CPHS responsibility under the law to possess such information.

Ms. Lund proposed addressing two categories of data: state data under CalHHS jurisdiction and data from external entities. She acknowledged the impracticality of maintaining up-to-date privacy practices for all CalHHS departments due to their numerous and evolving data sources. Therefore, she recommended that researchers provide CPHS with specific information about the data sources they are requesting.

Ms. Lund highlighted challenges arising when non-state data sources are linked with state data, particularly concerning privacy notices and informed consent practices of the non-state data. Without this information, CPHS reviewers find it difficult to determine the appropriateness of such linkages. She suggested that researchers should make reasonable efforts to supply CPHS with details about the privacy and consent practices of non-state data sources. While CPHS cannot mandate this information, researchers should indicate in their applications if obtaining it is not feasible. This approach would enhance the committee's ability to perform due diligence and make informed decisions, ultimately serving the best interests of the public.

Dr. Schaeuble emphasized that researchers should provide information on the privacy practices of non-state entities when seeking to link state and non-state datasets. This information would facilitate a smoother review process and potentially expedite project approval. Without such details, CPHS may find it challenging to justify data linkages, possibly affecting project approval.

Dr. Dinis expressed concerns regarding the consent process, particularly whether participants are informed about the future use of their data in research. She questioned how the Health Insurance Portability and Accountability Act (HIPAA) framework could assist CPHS in this context.

Ms. Kurtural noted that HIPAA offers a framework of considerations that could be integrated into regulations.

Ms. Lund highlighted two primary risks associated with merging large datasets:

1. Sharing Personal Identifiers: The inclusion of sensitive information like names and Social Security numbers poses significant risks if breached. CPHS can mitigate this by ensuring researchers request such identifiers only when absolutely necessary. Reviewers already inquire about alternatives to Social Security numbers, and CPHS could be more rigorous regarding the release of personal identifiers. In cases where these identifiers are essential for data linkage, CPHS should consider who performs the linkage, who retains the data, and whether personal identifiers can be removed post-linkage, resulting in an analysis dataset missing the personally identifiable information. Ms. Lund also suggested employing a third-party honest broker for linkage processes, ensuring that research teams receive only de-identified datasets. This approach would reduce risks in the event of a data breach, as the honest broker would destroy personal identifiers after completing the linkage.

2. Re-identification Risks in Large Datasets: Even after removing personal identifiers, the unique combination of data fields in extensive linked databases can potentially lead to re-identification of individuals. CPHS can address this by requesting researchers to submit a statistical analysis of re-identification from those data fields. While this analysis may not provide definitive answers, it would offer a probability range from very low to high risk, helping CPHS in making informed decisions.

Ms. Kurtural expressed concern about CPHS's limited talent and resources to implement the scoring methodologies, noting that it might be difficult for the committee to locate the necessary resources.

Ms. Lund clarified that researchers, not CPHS, would need to provide those resources.
Ms. Kurtural suggested involving the public in the decision-making process, given the high expectations placed on researchers. She also noted the existence of frameworks for categorizing different risk levels that could be utilized.

Dr. Schaeuble cautioned that relying on specific assumptions for analysis could be problematic, as applying a consistent set of assumptions across different situations might not be appropriate.

Ms. Kurtural proposed using a common unique identifier within the agency to avoid reliance on Social Security numbers, thereby addressing many concerns related to personally identifiable information (PII).

Ms. Lund noted that this approach would not address challenges related to merging large datasets.

Ms. Kurtural highlighted the distinction between research projects under IPA review that do not involve linking to external data and those that do. She expressed confidence that projects without external data linkage could be reviewed on an expedited basis. However, she emphasized that projects requesting to link state datasets with external datasets should undergo a full board review. She suggested specifying a two-tiered review process in the regulations to address this distinction.

Dr. Schaeuble asked Attorney Goldman for his perspective on the draft language being discussed.

Attorney Goldman explained that the first two requirements in the second section of his proposal aim to gather additional information to assess whether the privacy plan is sufficient. He suggested to take the first two considerations under the second section and turn into a process focused requirements to help CPHS determine whether the privacy plan is sufficient. This approach is not about determining whether consent is always required but rather about understanding the available information, its extent, and how it informs decisions about the adequacy of the privacy plan's safeguards.

Dr. Schaeuble inquired whether the last two items in the final section are already addressed by the Information Practices Act (IPA). Attorney Goldman advised that he review these items and provide feedback to the subcommittee.

Ms. Lund opened the floor to the public for comments on the proposed regulations.

Ms. Agnes Balla thanked the committee for allowing her to participate in the discussion. She introduced herself as a representative of the University of California, Office of the President, where she works with campus IRB directors on various human subjects research issues. Ms. Balla observed that CPHS has two roles: one under the Information Practices Act (IPA), which focuses on ensuring researchers' plans adequately protect data, and the other as an IRB, which involves balancing risks to participants and benefits to the public when reviewing research projects.

Ms. Balla used the example of the CURES database, a state database for prescription-controlled substances, to illustrate challenges in informed consent. She explained that obtaining consent from all individuals in the database would be impossible, as some may be transient or deceased. She mentioned that this example highlights potential confusion between CPHS's role under the IPA and its IRB responsibilities, noting that the materials provided before the meeting seemed more focused on the IRB role. She suggested clarifying the framework to address IPA-specific requirements and provide clear guidance on what criteria researchers should meet.

Ms. Balla also commented on earlier discussions about adding protections, such as using an honest broker or conducting statistical analyses. She noted that having an honest broker would place a burden on the agency, as the broker must be independent of the research team and have authorized access to the data. Regarding statistical analysis, she mentioned that researchers have attempted this before but found it to be very expensive and requiring specialized knowledge, which varies for each dataset.

Ms. Balla closed by offering to assist the subcommittee further and thanked them for the discussion.

Evan White offered a public comment to the subcommittee on the proposed regulations. Mr. White expressed gratitude to the committee for their dedication to data privacy and the issues discussed in these meetings. He voiced his belief that the exercise is misguided, assuming a non-existent problem. Mr. White observed that CPHS appears to be attempting to transform their IPA authority into an IRB authority, echoing the previous speaker's comments. He pointed out that the subcommittee's standards surpass current IRB standards. Mr. White argued that expanding CPHS's role is unnecessary since any human subject research already requires IPA approval and is reviewed by an IRB, which may be CPHS or another entity such as a University. Furthermore, he noted that all projects reaching CPHS via IPA have undergone agency review, with agencies being the rightful custodians of the data sets, as designated by the legislature. Mr. White highlighted that legislatures have established statutory frameworks addressing these issues, balancing privacy concerns with the benefits of data research. It is the agencies' duty to apply these criteria and standards. They undertake extensive processes to weigh the considerations outlined in these documents before deciding on a project's progression. Subsequently, projects undergo CPHS review for IPA, which is solely a data security check. Mr. White stated it is inappropriate for this process to be moving forward. He mentioned that agencies such as the Department of Education (DOE) or the Department of Justice (DOJ) would be astonished to discover that the projects they approved after a month-long rigorous review process could be overturned by this body based on the same criteria they have already assessed. He pointed out that this committee has previously criticized other Institutional Review Boards (IRBs) for inadequate reviews, which he found inappropriate. He said that the quality of their reviews is not the issue; the issue is the authority to conduct reviews under these standards, and in this instance, the other IRBs possess the authority, whereas this body does not.

Mr. White addressed the issue of informed consent. He argued that applying the concept of informed consent in these circumstances is misguided, both legally and policy-wise. He pointed out that the IPA discusses consent in other sections but intentionally excludes it from subsection P, which pertains to CPHS. Mr. White insisted that there is no legal basis within the IPA for enforcing an informed consent requirement. He reiterated, from a policy perspective, that many public datasets held by the government lack consent. For instance, individuals do not consent to the use of their birth records or emergency room data for later research purposes. Mr. White emphasized that the initial consent provided for these datasets does not meet the IPA's informed consent standards. He noted that legislatures have enacted laws allowing the use of data collected without proper informed consent for research. Many of these laws cover datasets reviewed by CPHS, restricting data access and usage. Legislatures have weighed personal privacy against research benefits, resulting in a framework enforced by agencies. Mr. White stressed that it is not within CPHS's remit to impose a requirement that the legislature did not deem necessary.

Mr. White remarked on the earlier discussion about researchers evaluating the data for potential re-identification risks after merging the datasets. He noted that the IPA is only relevant when the personal information, as defined by the statute, can be traced back to an individual. The data must be identifiable or easily re-identifiable. In cases where there is no risk of re-identification, the IPA does not apply, and thus, CPHS would not have purview over such situations.

Mr. White expressed his gratitude to the committee for their consideration. He acknowledged that his comments might not be particularly favorable to the process, but he wanted to emphasize his appreciation for the committee's dedication and recognized that all members are serving voluntarily.

C. Incorporation of Potential Revisions

Ms. Lund noted that the subcommittee had discussion of potential revisions discussed in agenda item B. Suggesting the following action items:

1) Attorney Goldman work with Dr. Schaeuble on language revisions for the second item on page 2.
2) Attorney Goldman will review items last two items of the last section to review if they are already covered by the IPA.
3) Ms. Kurtural committed to working with Attorney Goldman and Attorney Maggie Schuster to develop and outline for the next subcommittee to consider.

Dr. Schaeuble inquired if the subcommittee had any concerns about the sections of the document pertaining to the language used in the risks portion and sought feedback from CPHS. Dr. Dinis and Ms. Lund affirmed that CPHS's concerns were addressed.

Attorney Goldman proposed that the committee consider removing the last risk criteria, citing its subjective nature, and suggested that risk factors should be objectively ascertainable. The CPHS subcommittee agreed and decided to strike/eliminate the last risk from the document.

Ms. Lund opened the floor for public comment.

Ms. Agnes Balla inquired whether the public could submit written amendments to the document rather than verbal comments.

Dr. Rykaczewska, the CPHS administrator, informed Ms. Balla that she could send the edits to her email, which would be provided in the chat and would be also available on the CPHS website.

Motion:

It was moved by Ms. Lund and seconded by Ms. Kurtural to strike the last item (risk) in the second section. Dr. Schaeuble will work with Attorney Goldman to reword items 1 and 2. Ms. Kurtural will work with Attorney Goldman and Attorney Schuster to create an outline for the regulation's agenda. Attorney Goldman will review the last 2 items in section 3 to determine whether they are already included in the IPA.

Approve: Dr. Dinis, Dr. Schaeuble
Oppose: None.
Abstain: None.
Absent: None.

Total= 4 In Favor- 4, Opposed- 0, Abstained- 0

Dr. Rykaczewska, the CPHS administrator, proposed a deadline for the public to submit their edits two weeks prior to the next subcommittee meeting, with the date to be determined in the forthcoming agenda item.

Ms. Kurtural reminded everyone that the regulatory process includes a public comment period and emphasized that it is an extensive process. She assured that there is no need for concern over deadlines and encouraged the public to submit comments at any point during the process.

D. Next Subcommittee Meeting Date

The full committee is set to convene on Friday, October 4th, 2024. The subsequent sub-committee meeting is tentatively scheduled for Friday, November 14, 2024, but there is a possibility of rescheduling it to Friday, November 8th, 2024. Ms. Lund suggested that the sub-committee provide a briefing at every full committee meeting following the subcommittee meetings.

E. Adjournment

Ms. Lund expressed gratitude to all for their contributions and participation in the subcommittee, and she adjourned the meeting at 10:24 A.M. on September 13, 2024.