Memo on Suggested Framework for IPA Review Criteria

March 3, 2025

Dear CPHS Members,

I have reviewed the 8th draft of "Suggested Framework for Additional IPA Review Criteria" that will be presented to CPHS by the at its next full meeting on March 7, 2025. I feel it might be helpful to put my thoughts into writing before the meeting.

Background

The main issue that prompted the work of the Subcommittee is the concern that research requests for use of state-held data are not receiving adequate review. This is a very legitimate concern, and it is commendable that the Subcommittee has taken this issue seriously. The federal Common Rule, as interpreted by the federal Office of Human Research Protection (OHRP), does not provide for Common Rule review by the IRB of the institution that is releasing data for research. In the case of state-held data that IRB would be CPHS. Instead, OHRP has stated that Common Rule review is the responsibility of the IRB of the institution receiving the data. This is usually an IRB affiliated with the University of California or other academic institution. Because it is not "their" data, the receiving institution's IRB may not take its review role as seriously as the releasing institution's IRB. In fact, CPHS has found that most IRBs of receiving institutions designate data-only projects as "exempt" from review under the federal Common Rule. This results in most such projects not undergoing comprehensive review, including review of methodology, consent, ethical considerations, and other issues addressed in the federal Common Rule. For this reason, CPHS has been seeking ways to conduct more thorough reviews under its authority in Section t of the California Information Practices Act.

At the time that Section t of the IPA was amended in 2006 to require CPHS review for research data releases, OHRP had not yet issued its guidance clarifying that an institution releasing data is not "engaged" in the research. As the CPHS Chair in 2006, I remember that CPHS routinely reviewed data releases under the federal Common Rule. In 2008, OHRP issued guidance that institutions releasing data are not "engaged" in the research such that their IRBs could not use the federal Common Rule for review of these releases. When I stepped down as Chair in 2009, CPHS had not yet figured out how to deal with this issue. In fact, no attempts were made to incorporate OHRPs guidance into CPHS's Policy and Procedure document for many years, although some CPHS members, including myself, were concerned about conflicting information being presented to the public. One of the first things I did upon becoming Vice Chair was, with committee approval, to convene a subcommittee to address this. Dr. Lois Lowe, who had been my Vice Chair when I had been Chair, agreed to co-chair this effort. The subcommittee was scheduled to meet on December 10, 2021 (https://www.chhs.ca.gov/wp-content/uploads/2022/06/Accessible_December-10-2021-Subcommittee-Agenda.pdfdocument) but CPHS legal counsel requested that they take the lead.

At the February 3, 2023 full CPHS meeting (https://www.cdii.ca.gov/wp-content/uploads/2023/06/Minutes_February-3-2023_CPHS_Meeting_Minutes-Complete.pdf) CPHS's legal counsel, Jennifer Schwartz, presented the full committee with a new chart entitled "CPHS Review Pathways Decision Tree." She requested written feedback from CPHS members (I don't know if any was received) and a revised version of this chart was published on the CPHS website in July, 2023 (https://www.cdii.ca.gov/wp-content/uploads/2023/08/CPHS-Review-Pathways-Decision-Tree-Accessible-1.pdf). However, some members believed that CPHS should continue to operate under pre-2008 standards. These concerns were voiced at the March 1, 2024 meeting (https://www.cdii.ca.gov/wp-content/uploads/2024/08/March-2024-Meeting-Minutes.pdf).

A memo (https://www.cdii.ca.gov/wp-content/uploads/2024/06/CPHS-Memorandum-Common-Rule-and-IPA-for-Committee-FINAL-002.pdf) was subsequently issued by CHHS legal counsel on May 8, 2024 confirming that CPHS could no longer apply the federal Common Rule to data releases.

The Proposed Solution

The Subcommittee has taken the approach of using the "at a minimum" language in the IPA to allow it to create regulations specifying additional criteria for its reviews of data releases. The proposed framework designates 13 risk factors that CPHS may use to determine that a project is high-risk, and thus may be subject to additional scrutiny. In my opinion, these risk factors are so inclusive and vague that almost any project proposal to CPHS would fall under them. A prime example of over-inclusiveness is the risk factor: "vulnerable populations described in the 2018 Common Rule (45 CFR 46), including but not limited to children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. Virtually all CalHHS databases include such individuals in significant, if not exclusive, numbers. Examples of vagueness are the risk factors that designate "especially sensitive" physical health, psychological health, and social, economic and legal information. While these risk factors are illustrated with examples, all use "but not limited to" language that leaves the "especially sensitive" determination open to interpretation by the committee. Also, some risk factors exceed CPHS's technical knowledge to address, such as the risk factor: "The researchers plan to use technologies such as artificial intelligence and machine learning that may increase the risk of individuals being re-identified." CPHS does not have members or staff with sufficient technical knowledge to fully understand AI and machine learning and how they might affect reidentification.

The two additional scrutiny actions specified for projects with risk factors are overly vague. The first proposed actions are:

> # To the extent 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, [from a Notice of Privacy Practices or other communication about privacy,] [and the context or situation in which that information was provided], [and how that information was provided].

The use of the language “To the extent it is available” in the first action reveals that the Subcommittee believes that such information may not be available to the researcher or the reviewer. What would happen in this instance? Would the researcher or reviewer(s) be expected or allowed to carry out investigations to uncover this information? It is understandable that the research community would be concerned that this process could result in long and costly delays that may exceed grant deadlines and discourage research.

The second additional scrutiny action in the proposed framework is:

> # Information about which of the risks enumerated above are applicable in the research, and steps taken to minimize those risks.

This seems unnecessary given that the IPA states that CPHS’s review must assess whether use of specific data is necessary, and if it’s use is necessary, provides for measures that could be taken to minimize the risk.

> A) Determine whether the requested personal information is needed to conduct the research.
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> (B) Permit access to personal information only if it is needed for the research project.
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> (C) Permit access only to the minimum necessary personal information needed for the research project.
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> (D) Require the assignment of unique subject codes that are not derived from personal information in lieu of social security numbers if the research can still be conducted without social security numbers.
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> (E) If feasible, and if cost, time, and technical expertise permit, require the agency to conduct a portion of the data processing for the researcher to minimize the release of personal information.

As CPHS Chair at the time Section t of the IPA was amended in 2006, I believed that the intent of the legislature was to prevent security lapses, such as the breech of Department of Social Services data on a UC Berkeley researcher’s laptop in 2005 that motivated the amendment. Indeed, privacy is not even mentioned in Section t of the IPA. The language of Section t dealing with CPHS delegation of its review responsibilities to other IRBs only addresses data security.

> (5) The CPHS may enter into written agreements to enable other institutional review boards to provide the data security approvals required by this subdivision, if the data security requirements set forth in this subdivision are satisfied.
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> (6) Pursuant to paragraph (5), the CPHS shall enter into a written agreement with the institutional review board established pursuant to former Section 49079.6 of the Education Code. The agreement shall authorize, commencing July 1, 2010, or the date upon which the written agreement is executed, whichever is later, that board to provide the data security approvals required by this subdivision, if the data security requirements set forth in this subdivision and the act specified in subdivision (a) of Section 49079.5 of the Education Code are satisfied.

In summary, I believe that the proposed framework for new regulations is too broad and vague and would allow CPHS too much authority based on its subjective interpretations of privacy and security issues. Such broad and subjective judgements need to be guarded against since the IPA, like the Common Rule, does not provide for mechanisms of appeal for researchers beyond CPHS.

The proposed addition criteria also primarily address privacy protection concerns, not the data security addressed in Section t of the IPA. I do not believe that the Subcommittee's concentration on privacy is consistent with the legislature's intent for CPHS to address data security concerns only. I believe that the legislature did assume that privacy concerns would be addressed by an IRB (not necessarily CPHS) reviewing under the federal Common Rule. Unfortunately, as stated above, this is not happening consistently.

Possible Alternative

As the amount, granularity and sensitivity of data released from research databases increases along with the power of artificial intelligence and other tools, this lack of comprehensive review under the Common Rule is increasingly becoming problematic. Who is reviewing the methodology, consent, and other issues for such projects, even if they only involve data analysis? I would like to suggest a possible alternative to the Subcommittee's approach.

I believe that the IRBs of institutions receiving data have the discretion to conduct full Common Rule reviews for data-only research projects, rather than provide exemptions. Guidance on (Frequently Asked Questions: Limited Institutional Review Board Review and Related Exemptions | HHS.gov) the OHRP website states that, at a minimum, the IRB must conduct a limited review:

> D. The exemption for secondary research involving the use of identifiable private information or identifiable biospecimens for which broad consent is required (45 CFR 46.104(d)(8))
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> This exemption requires an IRB to conduct a limited review to make the determinations required by 45 CFR 46.111(a)(7); that is, to determine that, when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. Additionally, the exemption requires that an IRB conduct a limited review to determine whether the research to be conducted is within the scope of the broad consent that was obtained for the storage, maintenance, and secondary use of identifiable private information or identifiable biospecimens (45 CFR 46.104(d)(8)(iii)).

Before CPHS conducts an IPA review for some or all projects, perhaps it should require researchers to obtain evidence from their institution's IRB that it has conducted and approved the project under a full Common Rule review or has conducted a limited review before granting an exemption. CPHS could require this as a prerequisite to its IPA oversight for some or all data requests. Certainly, this approach would not fully address the concern that the IRBs of receiving institutions might not be as invested as CPHS in protecting state data. However, I believe most IRB members, regardless of the institution, take their responsibilities seriously when given the opportunity. However, I suspect that most of these data-only projects are being granted exemptions by IRB chairs such that they never reach members for full or limited review.

I believe this approach would shift more of the responsibility to the IRBs of receiving institutions, which is more consistent with federal law and may be more practical given CPHS's limited resources and authority under the IPA.

Unfortunately, this approach and the approach proposed by the Subcommittee would do little to address what I consider CPHS's greatest liability—its seriously limited ability to carry out its data security responsibility under the IPA. Members of the Subcommittee are correct in pointing out the artificial intelligence (AI) and other technological advances are placing the confidentiality of all databases at risk. At a minimum CPHS needs members and/or consultants with sophisticated knowledge of these technological advances and how to protect against them. Lacking this and other augmentations. the public might be better protected if CPHS's data security role was shared with or transferred to another state entity with adequate data security expertise.

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