
Public comment on draft CPHS regulations

From Evan B White <evanbwhite@berkeley.edu>

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To CHHS CPHS <CPHS@chhs.ca.gov>

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Dear Committee for the Protection of Human Subjects,

I write to express my strong opposition to the draft IPA regulations that your Committee is working on, and to express my concern that certain members of your Committee are unduly hostile to research using state administrative data. Such research is in the mainstream of social-science research and is receiving excessive scrutiny from certain members of the CPHS.

My name is Evan White and I am the Executive Director of the California Policy Lab, a research institute based at the University of California that specializes in working with government agencies to do policy-focused research that helps improve the lives of Californians. We specialize in working with sensitive government data and have set up over 50 data-use agreements with government agencies at the state and local levels throughout California. We work with over 300 researchers and are facilitating nearly 200 active research projects. We run a Secure Data Hub and a leading-edge compliance system, which enables us to host person-level data on education, justice involvement, homelessness, health, household finances, and more. Privacy is central to our mission and we go to great lengths to protect the privacy and identity of individuals in our datasets.

Many important policy issues cannot be studied without access to person-level data and many more cannot be studied with only one dataset, but instead require the linking of data across different government agencies. CPL has advanced expertise in linking pre-existing administrative datasets. We have published [a toolkit](#) on that subject and have also won a [National Science Foundation grant](#) for our data linkage efforts. Such data linkages are more and more common in social-science research, and are also the subject of ongoing statewide efforts in California, including substantial state investments in [the Cradle-to-Career Data System](#) and the [CHHS Agency Data Hub](#). These data linkages are crucial for breaking down silos between different domains and to understanding complex issues like homelessness or health, which have many social determinants. As a consequence, data linkage is now a core feature of much social-science research.

Research using pre-existing data does not carry the same risks as research involving live human subjects, which is why the federal regulations governing IRBs (the Common Rule, 45 CFR 46) generally exempt research using pre-existing data under 45 CFR 46.104(d)(4). Consent is often impracticable for large administrative datasets that include thousands if not millions of observations. Yet the research value is substantial, which is why government data is now so [commonly used](#) in academia.

Unfortunately, some members of the CPHS seem to misunderstand these laws and scientific trends. The [latest draft of the proposed IPA regulations](#) indicate a bias against projects that use state data, and a misguided belief that the initial consent provided upon the data's collection is a relevant factor. For example, those rules would allow a CPHS reviewer to stop a project simply because it used income data, one of the most common outcomes in social science research. They would also allow projects to be rejected simply for using linked data or health data.

Perhaps most alarmingly, they would allow projects to be rejected based solely on the adequacy of initial consent for pre-existing data. Such an inquiry is not appropriate and flies in the face of existing federal IRB guidance, which does not require consent for pre-existing data so long as the data are appropriately anonymized and no efforts are made to contact the people represented in the data. Practically speaking, a consent requirement is entirely infeasible for datasets with millions of observations and would scuttle any project using large administrative datasets.

A consent requirement for pre-existing data also makes no sense from a policy perspective. CPHS's regulations would build a barricade on a road that already has guardrails. The draft regulations imply that CPHS can supplant the carefully considered decisions of federal and state legislatures who have already set up guardrails for these data. Those lawmakers are perfectly aware that when such data are collected, individuals do not consent to the broad array of uses to which the data may later be put (indeed, in some situations, like at birth or in the emergency room, such data are collected without any consent at all). That's why those lawmakers have considered and enacted laws that put guardrails on such datasets. Those laws often circumscribe who can access the data (eg, Cal. Penal Code 13202), for what projects it can be used (eg, Cal. Revenue and Tax Code 19552), and what procedures need to be followed in using the data. In passing these laws, lawmakers weigh the various public interests at play, including the privacy interests of the people represented in the data and the potential value that research could provide to public knowledge and effective policy.

CPHS's draft regulations essentially discard the duly enacted laws of our elected representatives. Instead, they replace such laws with their own views as to what should be allowed. Does the federal law governing education data (FERPA) require special scrutiny when linking on earnings data? No, it doesn't -- but under these new rules, that would be an acceptable basis for rejection. Does the California Penal Code require that projects using criminal records get individual consent? No, it doesn't -- but under these new rules, CPHS could require it. Members of the CPHS are entitled to their policy views, but they are not endowed with the authority to elevate their views above those of elected legislatures. And the consequences for research would be devastating.

Unfortunately, our concerns don't end with the draft regulations. We have witnessed conduct along these lines from certain members of the CPHS before. The prior statements of certain members, and their disregard for adhering to their delineated authorities (even after advice of counsel), lead us to the conclusion that the CHHS Secretary should consider membership changes at CPHS. Examples can be found at 1:17–1:35 of the March 2024 CPHS meeting recording and 0:51–1:02, 1:06–1:08, and 1:43–1:45 of the June 2023 CPHS meeting recording, though there are other examples that we could bring forward from other recent meetings.

In summary, I urge the CPHS to drop its current IPA rulemaking effort, and I recommend that the CHHS review current CPHS membership to ensure that all members will adhere to the letter and spirit of the laws they implement. Thank you for your consideration in this matter.

Sincerely,
~Evan White

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Evan White
Executive Director, California Policy Lab @ UC Berkeley
evanbwhite@berkeley.edu | he/him/his | 626.524.5463 c