1901 41st Street
Sacramento CA 95819

March 7, 2025

Committee for the Protection of Human Subjects

RE: Comment on proposed changes to IPA review criteria (fifth draft).

Dear Committee members:

I am writing to request that you **do not** expand CPHS discretion to deny research requests made under the IPA as recommended in the current fifth draft of proposed changes.

I am a primary care physician and researcher at University of California Davis. I am writing in my personal capacity. I have led multiple federally funded research projects to understand risks of unsafe opioid prescribing, overdose risk, and substance use treatment in California. These projects have been funded by many agencies (NIH, CDC, US Dept of Justice, California Dept of Public Health, Patient Centered Outcomes Research Institute) and have used multiple state data sets, including vital records from CDPH, prescription data from California Departments of Justice and Health Care Services, and hospital utilization data from HCAI.

Many of these projects have involved linking person-level data from more than one state agency. These projects have helped to evaluate California's overdose prevention projects and policies and provided important information for California state agencies and the public. All these projects have involved minimal risk to patients; with the only substantive risk being possible loss of confidentiality.

Many types of research projects require complete data about every person who meets a certain cohort definition in order to draw rigorous and unbiased conclusions. **Requiring patient-by-patient consent would block huge amounts of beneficial research.** This includes research that evaluates public policy or public health programs, research that evaluates system- or county-level interventions, and research into healthcare disparities and inequities, to name just a few important categories. In almost all cases, it is not possible for researchers to contact every individual to obtain retroactive consent. To give just some examples from my research:

- The requirement to obtain retroactive consent would mean contacting all patients who received any opioid prescriptions in California over several years, which is millions of patients per year. The process to even try to contact each patient would cost many times more than the entire research project.
- Most retrospective records I use for research only contain patient address; there is no way to email or call patients to obtain consent, and many patients move so addresses get out of date quickly.
- The process of finding contact information and contacting patients / trying to contact patients (even if it were feasible) would pose a MUCH greater threat to privacy than the actual research projects I conduct.
- I do research on overdose prevention. Many of the patients whose records I examined for my research studies have died and so cannot give permission.

The current privacy safeguards required by CPHS and individual California state agencies are comprehensive and thorough including for research that involves linking patients across multiple databases. The benefit of rigorous research for public health, public safety, and improving the quality of lives for Californians far outweighs the minimal risks related to possible loss of confidentiality. The risks to research posed by CPHS-approved research is much less than the risks to privacy Californians face in everyday life by, for example, ordering and paying for items online, using public Wi-Fi, and signing up to mailing lists.

The federal common rule already establishes clear standards and procedures for approving research, including research where a waiver of informed consent or waiver of HIPAA authorization is granted. **There is no need to re-invent the wheel**. One of the CPHS members stated during the public meeting on March 7 that many CPHS members are not well informed or educated about standard research practices and privacy safeguards that researchers follow. Members who do not understand the basic federal and state laws and regulations already in place should not approve or create new procedures for approving research studies.

Expanding CPHS authority to deny research projects for "sensitive" topics reinforces stigma and will harm patients with those topics by preventing important research. For example, blocking research on drug use or addiction that already has appropriate patient safeguards in place just because addiction is a sensitive topic will have the unintended effect of identifying ways to improve the lives of patients struggling with drug use or addiction.

If CPHS does adopt new regulations and authorities to block research arbitrarily, these new rules should not be applied to researchers at University of California, California State Universities, or other non-profit universities and research institutions in California. University-based academic researchers must maintain rigorous training regarding responsible conduct of research and patient safety, and typically also must get approval from their local IRBs in addition to approval from CPHS. While CPHS might be appropriately skeptical about research requests from for-profit or foreign organizations, research conducted by non-profit universities in California already have many additional layers of privacy and patient protection to minimize risk of patient harm or loss of privacy.

The proposed IRB fee structures are wasteful and should not be adopted. CPHS should not adopt a fee structure where the majority of the money goes to the cost of collecting fees. The additional money provided by IRB fees (minus the collection costs) is budget dust that state agencies should be able to find easily via minimal appropriation requests. If fees are charged, then researchers at public agencies (University of California, California State University, individual state agencies and departments…etc) should be exempt from those fees. The CPHS application process is already incredibly time consuming and costly for researchers and serves as a major "tax" that prevents many researchers from submitting applications. Increasing this tax by charging IRB fees would further harm Californians by blocking even more important and much needed research.

Thank you for considering my comments. Please email or call if you have any questions.

Sincerely

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