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Dear CHHS Committee for the Protection of Human Subjects:

I appreciate your dedication to the Committee work, and have great respect for your important role – I have served as a CPHS member at University of California, Berkeley, and I understand the commitment that this requires. I attended your sub-committee meeting today (9/13/24) and I am writing to express my serious concerns about the regulations that the Committee is exploring.

I am a Professor of Epidemiology at University of California, Berkeley, and I conduct research on questions related to a range of topics using California data, including projects that examine maternal and infant health, and projects on injuries and deaths due to community violence. There are substantial benefits to California from work that helps us understand how we can reduce violence, and improve wellbeing for both mothers and infants, and my research is pertinent to these topics. For example, we carried out a rigorous evaluation of a novel violence prevention program (link to the research: https://ajph.aphapublications.org/doi/10.2105/AJPH.2019.305288) and our findings were considered key evidence at a White House committee considering strategies to reduce violence. Preexisting administrative data and linkages of these data are essential to my research, and essential to supporting many other projects that are providing evidence-based strategies to improve health in California and beyond.

The draft of regulations shared in the meeting was very worrisome due to the vague and broad language that would be difficult for researchers to effectively navigate, and difficult for the Committee to apply fairly across projects. Additionally, there was discussion of requiring certain aspects of risk to be quantified by researchers that is impractical if not impossible. Overall, these changes have the potential to dramatically compromise the ability of researchers to answer important question using state data. I cannot imagine that creating barriers to important and beneficial research projects is the appropriate role for this Committee.

It also seems that adding these regulations is not an appropriate application of authority under the IPA. Other members of the community spoke eloquently about this problem in the meeting, and it seems adopting regulations like these would be an inappropriate overreach of the authority of the committee.

I appreciate your consideration of these concerns.

Sincerely,

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Jennifer Ahern