

From: Ambar La Forgia <ambar@berkeley.edu>

Sent: Friday, February 28, 2025 9:03 AM

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

Subject: Voicing opposition to the proposed regulations under the IPA

Dear CHHS Committee for the Protection of Human Subjects,

I'm writing to express my opposition to the proposed regulations that the Committee is exploring.

My name is Ambar La Forgia and I am a researcher at UC Berkeley. My research focuses on how changes in healthcare ownership and increasing consolidation impact patient access to high-quality affordable healthcare. To conduct my research, I rely on data collected by government agencies who then make that data available to researchers. For example, using that data, I am currently examining how hospital mergers and acquisitions in California have impacted consumer medical debt, especially focusing on vulnerable or marginalized populations.

I was concerned to learn that certain members of CPHS are pursuing regulations that could impinge on research using government-held data. Such data are at the core of modern social-science research and the Common Rule has long recognized that research using such pre-existing data sources should be afforded less scrutiny because it does not involve live contact with human subjects.

Instead, the new rules would go back and check the consent at the time of data collection, which contradicts how the Common Rule deals with pre-existing data. Many of these datasets have no initial consent (eg, consent is not offered at birth), which is why the Legislature has balanced the equities and put in place statutes that restrict the availability and use of such data for research. The CPHS should not – and don't have the authority to – substitute their own private views on privacy for those of our elected representatives.

I oppose the new regulations.

Sincerely,

Ambar La Forgia

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