

May 6, 2024

To: CalHHS Secretary Mark Ghaly

CC: CalHHS Undersecretary Marko Mijic
CalHHS Chief Data Officer and CDII Director John Ohanian
CPHS Chair (interim), and CHHS Assistant Secretary, Darci Delgado
CPHS Vice Chair, Larry Dickey
All other CPHS members

Subject: Issue arising at the Committee on the Protection of Human Subjects

Dear Secretary Ghaly:

We are a coalition of researchers and other practitioners that care deeply about the operation and effectiveness of California's government agencies and their impact on residents of the state. We are strong believers in, and practitioners of, ethical research, and want the state to reflect those values in its institutions. Most of us have used government administrative data in our research, often in partnership with state agencies, and many of us focus our research on the evaluation of public programs and policies because we believe that taxpayer dollars should be spent wisely and we should know how our programs and policies affect Californians. Our research using state data leads to better outcomes for the state and its residents.

We write today to express concerns about changes being proposed by certain members of the CalHHS Committee for the Protection of Human Subjects (CPHS). We are concerned that they are proposing to expand CPHS authorities beyond current law and that they are doing so as a way of imposing new consent requirements on the use of administrative data. These changes would grant CPHS IRB authority over projects that are already under the purview of other IRBs. The proposed changes would therefore be redundant in addition to being unlawful.

To explain a bit more about our concerns, CPHS has two distinct sources of authority: (1) it is authorized to conduct IRB reviews (i.e., Common Rule reviews) for CalHHS projects under its federalwide assurance; and (2) it is authorized to conduct data-security reviews under the California Information Practices Act (IPA) when a state agency discloses "personal information". Each authority involves a different type of review and a different breadth of projects (though sometimes those jurisdictions overlap).

At the March 1st CPHS meeting, members of the Committee proposed to expand the first authority to cover all projects falling under the second authority. In other words, they proposed to expand CPHS's IRB authority to include all projects brought to them under the

IPA.¹ These members made clear that their reason for proposing these changes was to impose new individual-level consent requirements when administrative data is released by California state agencies.²

We are deeply concerned about these changes. On legal grounds, these changes are outside the scope of the Committee's jurisdiction and contrary to established IRB regulations. They would also impinge on the existing jurisdiction of other IRBs, which are required to be in place at all research institutions like universities. On policy grounds, these changes would effectively disable many (if not most) projects using state administrative data because individual consent is not practicable for studies with thousands or millions of subjects. Such changes would thus limit any rigorous evaluation of state policies and programs on individual outcomes. Our colleague, Evan White, Esq., expands on these concerns in a separate memorandum.

Stemming from these concerns, we respectfully request the following:

- We urge you not to expand CPHS's authorities beyond what is clearly articulated in current law. Specifically, we ask you not to grant CPHS new authority to conduct Common-Rule review of applications that are submitted for IPA-only review. This is beyond their jurisdiction and is already covered by existing IRBs.
- We request that you invite research representatives to future meetings on this topic. Our voices were notably absent from the March 1st meeting and we would be substantially affected by these decisions.

Sincerely,

Signatories (in alphabetical order):

Prof. Jennifer Ahern, UC Berkeley
Prof. Abhay Aneja, UC Berkeley
Prof. Natalie Bau, UCLA
Prof. Hiram Beltran-Sanchez, UCLA
Prof. Mia Bird, UC Berkeley
Prof. Marianne Bitler, UC Davis
Prof. Sandra E. Black, Columbia University
Prof. Asa Bradman, UC Merced
Prof. Eleanor P. Brown, Pomona College
Prof. Tim Bruckner, UC Irvine
Brenda Bustos, PhD student, UC Irvine
Prof. Joan Casey, University of Washington

¹ See 1:16, 1:34, 1:40, and 2:43 of the March 1, 2024 CPHS meeting recording.

² See 1:17–1:35 of the March 1, 2024 CPHS meeting recording.

Prof. Yu-Ling Chang, UC Berkeley
Prof. Alec Chan-Golston, UC Merced
Prof. Susan Cochran, UCLA
Kimberly Coleman-Phox, MPH, UC San Francisco
Prof. Lara Cushing, UCLA
Prof. W Bowman Cutter, Pomona College
Prof. Stefano DellaVigna, UC Berkeley
Prof. Jeffrey Denning, University of Notre Dame
Prof. Carlos Dobkin, UC Santa Cruz
Prof. William Dow, UC Berkeley
Prof. Charlie Eaton, UC Merced
Prof. Daniel Eisenberg, UCLA
Prof. David Eisenman, UCLA
Prof. Robert Fairlie, UCLA
Dr. Sharon Farrell, UC Berkeley
Prof. Avi Feller, UC Berkeley
Prof. Lia Fernald, UC Berkeley
Dr. Brett Fischer, Mathematica
Prof. Jonathan Fuchs, UCSF
Prof. Ashvin Gandhi, UCLA
Prof. Alison Gemmill, Johns Hopkins University
Sneha Ghimire, Phd student, UC Merced
Prof. Sidra Goldman-Mellor, UC Merced
Prof. Julia Goodman, Oregon Health and Science University-Portland State University
Prof. David B. Grusky, Stanford University
Prof. Sandie Ha, UC Merced
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Prof. Rita Hamad, Harvard University
Prof. David J. Harding, UC Berkeley
Prof. Hilary Hoynes, UC Berkeley, Gov. Newsom's Council of Economic Advisors
Prof. Emiliano Huet-Vaughn, Pomona College
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