December 17, 2024

To: CalHHS Secretary Kim Johnson
CC: 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
RE: Concerns regarding proposed initiatives of the Committee on the Protection of Human Subjects (CPHS)

Dear Secretary Johnson,

We, the undersigned, are leaders in cancer population sciences at California's NCI-funded cancer centers. California has the most NCI-funded cancer centers of any state, and much of the population sciences research that our cancer centers conduct is based on, uses, and/or is informed by, California Cancer Registry data. California research institutions receive over $5 billion per year in cancer research from the National Institutes of Health. Restrictions on the access to and use of California Cancer Registry data for cancer research would have a material, negative impact on this substantial funding stream, the science it supports, and the steady progress toward better cancer treatments and prevention discoveries that California's researchers are advancing each day.

We write today to express concerns about and to oppose certain changes that we understand are being proposed within the CalHHS Committee for the Protection of Human Subjects (CPHS). We are concerned that the proposals will expand CPHS authority beyond its legal mandate, including imposing new consent requirements on the use of administrative data that will unduly burden research. The proposed changes would also grant CPHS IRB authority over projects that are already under the purview of other IRBs. This redundancy would run counter to the efficiency gains of the 2018 revisions to the federal Common Rule and the implementation of single IRB review. The CPHS is charged under the IPA (Section 1798.24) with oversight of individually identifiable information resourced from state agencies as a pairing of the state's data security interests to existing human subjects standards under the federal Common Rule. While the IPA contains specific requirements for responsible access, use, disclosure and redisclosure of state data, it contains no provisions regarding the methods and ethics of research protocols—such as informed consent—that are the purview of the IRB oversight under the Common Rule. As such, the IPA provides no justification, support, or rationale for CPHS oversight to depart from Common Rule requirements (including levels of review) associated with interactions or interventions with human subjects, or engagement with human subjects data in the context of a research protocol.

We write also in opposition to CPHS's proposal to impose fees on CPHS applicants. IRBs typically only impose fees on private industry, not on academic researchers. Some IRBs are beginning to impose fees to serve as the single IRB of record--given the extensive volume of review and work associated with multiple IRBs, but such institutions are not charging researchers for protocol reviews outside of single IRB. The fees proposed by CPHS are exorbitant and will have the effect of discouraging under-resourced researchers, as well as early-career researchers, from using valuable state administrative datasets. And by your own analysis, the benefit of the fees would largely be expended by the costs of collecting the fees themselves.

We applaud the entire Committee for its service, as we understand that volunteering for CPHS is a heavy lift with little reward. And the function of the Committee is vital – we value the role of the CPHS as the gatekeeper to research using certain government datasets. We urge all Committee members to honor the authorities granted them under law, the limits of those authorities, and the ethical duty to avoid interference from privately held views in the discharge of their responsibility to objectively review research under defined criteria.

Sincerely,

Signatories (in alphabetical order):

Saro Armenian, DO, MPH, Co-Leader, Cancer Control and Population Sciences Program, Director, Center for Survivorship and Outcomes in the Hematologic Malignancies Research Institute, City of Hope Cancer Center

Alan Ashworth, PhD, President, Helen Diller Family Comprehensive Cancer Center, Senior Vice President for Cancer Services, UCSF Health, UCSF

Melissa Bondy, PhD, MS, Associate Director, Population Sciences, Stanford Cancer Institute, Stanford University

Myles Cockburn, PhD, Co-Leader, Cancer Control Program, Norris Comprehensive Cancer Center, University of Southern California

Wendy Cozen, PhD, Deputy Associate Director, Population Science & Cancer Control, Chao Family Comprehensive Cancer Center, UC Irvine

Robert Hiatt, MD, PhD, Associate Director, Population Sciences, Helen Diller Family Comprehensive Cancer Center, UCSF

Theresa Keegan, PhD, MS, Co-Leader, Population Sciences and Health Disparities, UC Davis Comprehensive Cancer Center, UC Davis

Allison Kurian, MD, MSc, Co-Program Director, Population Sciences Program, Stanford Cancer Institute, Stanford University

Primo N. Lara, MD, Director, Executive Associate Dean, UC Davis Comprehensive Cancer Center, UC Davis

Sunmin Lee, ScD, Co-Leader, Cancer Control Program, Chao Family Comprehensive Cancer Center, UC Irvine

Caryn Lerman, PhD, Director, Norris Comprehensive Cancer Center, University of Southern California

Scarlett Lin Gomez, Co-Leader, Cancer Control Program, Helen Diller Family Comprehensive Cancer Center, UCSF

Diana Miglioretti, PhD, Co-Leader, Population Sciences and Health Disparities, UC Davis Comprehensive Cancer Center, UC Davis

V. Wendy Setiawan, PhD, Co-Leader, Cancer Epidemiology Program, Norris Comprehensive Cancer Center, University of Southern California

Heather Wakelee, MD, Deputy Director, Stanford Cancer Institute, Stanford University

Shehnaz Hussain, PhD, ScM, Associate Director, UC Davis Comprehensive Cancer Center, UC Davis

Mariana Stern, PhD, Associate Director, Population Sciences, Norris Comprehensive Cancer Center, University of Southern California

Sora Tanjasiri, DrPH, MPH, Associate Director, Cancer Health Disparities and Community Engagement, Chao Family Comprehensive Cancer Center, UC Irvine

Jennifer Tsui, PhD, Co-Leader, Cancer Control Program, Director of Cancer Care Delivery Research and Implementation Science, Norris Comprehensive Cancer Center, University of Southern California

Richard A. Van Etten, MD, PhD, Director, Chao Family Comprehensive Cancer Center, UC Irvine