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Dear CalHHS Committee for the Protection of Human Subjects,

I write to provide public comment on the [latest draft](#) of the proposed regulations under the Information Practices Act. My name is Tim Bruckner; I am a Professor and Chancellor's Fellow of Public Health at UC Irvine. For over 20 years, I have worked on state- and federally-funded projects using the CA birth file. I also recently served on the CA Vital Statistics Advisory Committee (VSAC) in which we reviewed data applications to work with State-collected data. It was an honor to serve on VSAC because their role in protecting individual privacy and promoting data security, while also facilitating transformational research that improves the lives of Californians, is a crucial one.

My own work includes collaboration with the California Perinatal Quality Care Collaborative. I have published over 40 articles focusing on efforts to reduce racial/ethnic disparities in perinatal outcomes, including for fetal death, intrauterine growth restriction, preterm birth, neonatal mortality, and Sudden Infant Death Syndrome. To conduct my research, I rely on data collected by government agencies who then make that data available to researchers. Using that data (the CA Birth Cohort File, for instance), my research has identified critical areas in the healthcare and social services infrastructure that contribute to non-Hispanic Black birthing persons' adverse perinatal outcomes.

I was concerned to learn that certain members of CPHS are pursuing regulations that could impinge on research using government-held data, such as the CA Birth Cohort File. Such data are at the core of modern epidemiological research. The Common Rule has long recognized that research using such pre-existing data sources should be afforded less scrutiny because it in no way involves 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 (e.g., 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. Indeed, much valuable research would simply not be possible if these proposed restrictions were put in place. The CPHS should not substitute their own private views on privacy for those of our elected representatives.

I oppose the new regulations.

Sincerely,

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