From: Ben Mooso <bmooso@berkeley.edu>
Sent: Wednesday, March 5, 2025 11:15 AM
To: CHHS CPHS <CPHS@chhs.ca.gov>
Subject: Public Comment for March 7th Meeting

I write to provide public comment on the latest draft of the proposed regulations under the Information Practices Act.

My name is Ben Mooso and I am currently an IRB Specialist at UC Berkeley and a resident of the great state of California. I was formerly the IRB Director at UC San Diego and Associate Director at UC Davis. The last 12 years of my career have been devoted to the protection of human subjects. I have navigated the complex gray areas of the regulations and ethics associated with the work we all do. To be clear, I applaud the entire Committee for its service. Volunteering for CPHS is a heavy lift with little reward. And your function is vital – the CPHS acts as gatekeeper to research using certain government datasets.

As a colleague in this work, 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 and biomedical research and the Common Rule has long recognized that research using such pre-existing data sources and/or data sources collected for non-research purposes should be exempt from the regulatory requirements including consent. The Revised Common Rule expanded these exemptions to cover most cases of research which uses data which is recorded in a manner that the individuals cannot be readily identified by the researcher (a different and less stringent standard than the 18 identifiers specified in HIPAA) or when the data remains protected under the HIPAA privacy rule. These changes came only after significant public consultation and rulemaking procedures.

When not exempt, the Common Rule has long held provisions for the waiver of the requirement for informed consent when certain conditions are met. The most tricky of these conditions to satisfy has generally been the requirement that the research could not be practicably carried out without the waiver. Yet, in the case of secondary research, this condition is nearly always satisfied because of the large scale of the data, the age of the data, and the lack of ability to contact the individuals to seek their consent given the limited data provided to the researcher. In fact, with the advent of the Revised Common Rule, asking for additional identifiers for the sole purpose of going back to obtain consent would be in direct opposition to the waiver criteria asking for justification of each piece of identifiable information with the intent to minimize the amount of identifiable information released to researchers to minimize the risks of a breach of confidentiality and invasion of privacy.

In contradiction to these long standing norms, the new proposed 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. The CPHS should not substitute their own private views on privacy for those of our elected representatives.

From an ethics perspective, this question asks us to weigh the principle of Respect for Persons against the principles of Beneficence and Justice. While we would all like to satisfy all three principles, we know that this is not always possible and secondary research using pre-existing data is one of the times when we must engage in balancing. While additional scrutiny is warranted to protect privacy and

confidentiality (i.e. limited IRB review) a full on requirement for informed consent puts these principles out of balance.

I oppose the new regulations.

Sincerely,

Ben Mooso, MS, CCRP

IRB Specialist
Office for Protection of Human Subjects (OPHS)
University of California, Berkeley
http://cphs.berkeley.edu
bmooso@berkeley.edu