From: Judy Rees <jrees@crgc-cancer.org>
Sent: Thursday, March 6, 2025 12:55 PM
To: CHHS CPHS <CPHS@chhs.ca.gov>
Subject: Opposition to Proposed Regulations

I am writing as a cancer epidemiology researcher and in my role overseeing the Cancer Registry of Greater California, to strongly oppose CPHS' proposed draft regulations that would create several, substantial barriers to the conduct of cancer research in California – barriers that are not necessary because there are other, better solutions.

In the Committee's role of protecting the interests of human subjects, perhaps it is easy to forget one major interest of the more than 190,000 Californians every year who are diagnosed with cancer and the more than 60,000 Californians every year who die of cancer. That is, making their experiences count. Rarely in observational studies is there a direct benefit to an individual, but large datasets like the California Cancer Registry are hugely valuable and inform a wide variety of clinical, epidemiological, public health and other programs. Their loss in research – which is where the proposed rules are taking us – would be a huge loss to California and beyond. CPHS should not be acting as a gatekeeper or a toll collector, but rather as a champion of research and a steward of very important datasets that make the experience of individuals count, especially in the context of minimal risk research involving de-identifed data.

1. Please would the Committee provide data on the history of CPHS' experience, specifically, how many examples has the Committee recorded of unsatisfactory or low quality research, or unauthorized reidentification of individuals, etc, that raised concerns prompting the new proposal for rule changes? If instead the proposed rules are the result of hypothetical perceived problems, can the CPHS confirm this?

2. Most of the proposed rule changes center around the risk of loss of confidentiality. Yet there are better ways to enforce the protection of confidentiality than blocking research, such as:

- A signed data use agreement – a legal document that commits the investigator to complying with confidentiality requirements. Data use agreements typically include provisions that preclude any attempt to reidentify individuals, a commitment not to re-release data to other parties without permission, and written assurance that the data will be held securely (using physical, technical, and administrative safeguards that the committee can review). Financial/legal penalties can be applied for breach of this agreement.

- Documentation of all individuals in the study team who will access the data and signed agreements by those individuals to comply with confidentiality requirements.

With these tools, the risk of re-identification of individuals is much, much lower than apparently perceived by the Committee members because the deidentified data will be held securely by a known researcher with clearly stated, good intent.

3. The fee schedule in the proposed rules is discriminatory and excessive – creating yet another barrier to research that particularly penalizes students, junior investigators, and non-state investigators. How will the funds generated by this new fee schedule be spent? Is it acceptable to the State legislature that this review process will generate profit? Unlike a commercial IRB, CPHS is working on behalf of the State to oversee State data use; it would be unfortunate for everyone if the Committee were perceived in the public eye as selling access to State data.

4. The following language from the proposed rules puts a large burden on the investigator:

- *"When the data were originally collected, the individuals were not told that their information would be used for research.*
- *When the data were originally collected, the individuals were not told that their information would be linked to data from other sources.*

Applications to CPHS for an IPA review shall include the following information, when any of the risks enumerated above are applicable in the research: To the extent it is available for the data sources to be used in the study, what information was given to individuals when their data was collected about the possible use of that data in research."

Insofar as datasets are owned and/or overseen by the State, it is neither efficient nor reasonable to require investigators to provide the information described above. These issues should be resolved "in-house" at the State level in terms of its policies for data collection. If CPHS has doubts about whether individuals were notified about future data uses, the Committee should obtain this information from the HHS data steward and do so as an oversight function, with consistency, rather than requiring every investigator who applies to CPHS to independently source and provide this information. I also hope the Committee will clarify that they will accept a statement of the general mechanism of information distribution in satisfaction of the ethical obligations of transparency and communication — outward expressions in lay language intended to provide every individual in a database (regardless of how many thousands or millions of individuals may represented therein) with meaningful and relevant information.

Thank you for considering my concerns about the proposed rules.

Sincerely,

Judy Rees, BM, BCh, MPH, PhD
Principal Investigator/Executive Director
Cancer Registry of Greater California (CRGC)
Public Health Institute
jrees@crgc-cancer.org

Associate Professor of Epidemiology
Geisel School of Medicine at Dartmouth College