



OFFICE OF THE VICE PRESIDENT – RESEARCH AND INNOVATION

OFFICE OF THE PRESIDENT  
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March 5, 2025

Catherine Hess, Ph.D., M.Phil.  
Chair, Committee for the Protection of Human Subjects  
Chief, Epidemiology and Evaluation Unit  
California Health and Human Services Agency  
1215 O Street, 11th Floor  
Sacramento, CA 95814

**RE: Public Comment on Suggested Framework for Additional IPA Review Criteria**

Dear Chair Hess:

I, together with the undersigned supporters, write on behalf of the University of California (UC) system to express our continued concerns on the [suggested framework for additional Information Practices Act \(IPA\) review criteria \(Ninth Draft\)](#) developed by the Committee for Protection of Human Subjects (CPHS) Subcommittee.

The UC system is the state of California’s research arm. It is comprised of ten research-intensive campuses, six medical schools, and three affiliated U.S. Department of Energy national laboratories.

The UC system previously [submitted public comments](#) on the suggested framework for IPA review criteria to former CPHS Interim Chair Dr. Darci Delgado on October 31, 2024 asking CPHS to provide a checklist for its stakeholders rather than propose rulemaking that would expand the IPA role of CPHS. Since our public comments, the subcommittee working on the IPA review criteria has continued forward with the drafting on the framework.

We are concerned that the suggested framework may lead to duplicative reviews alongside existing Institutional Review Board (IRB) processes, resulting in inefficient use of resources. The suggested framework also will create delays in critical time-sensitive research projects. Finally, we believe the suggested framework extends beyond the IPA and does not provide clear guidelines on how these factors will be consistently applied for IPA data only projects. This letter reiterates our request that CPHS refrain from proceeding with the proposed framework. We explain our concerns below.

## I. Potential for Duplicative Review

The suggested framework blurs the distinct role of CPHS as the body responsible for reviewing research proposals that request to use state-held personal information under [Civil Code section 1798.24\(t\)](#) and CPHS's separate role as the IRB for the California Health and Human Services Agency (CalHHS). This overlap is particularly concerning when researchers are already subject to IRB review by their own institutions. The introduction of an IPA review by CPHS, encompassing ethical criteria already carefully assessed by well-trained institutional IRBs, raises concerns about redundancy. This overlap could lead to confusion, conflicting reviews and recommendations, and administrative burdens for researchers and the state.

## II. Impact on Research Efficiency

The expanded IPA review criteria outlined in the suggested framework could unintentionally impede the progress of critical research projects. When multiple oversight bodies, such as IRBs and CPHS, provide conflicting recommendations, researchers are forced to navigate a back-and-forth process to reconcile differing requirements and secure alignment from all parties. This added complexity could delay research and divert valuable resources from the studies themselves.

In addition, delays could affect time-sensitive studies and the timely dissemination of research findings that are crucial for informing public policy and advancing scientific knowledge. Such delays are particularly concerning given the pressing societal challenges that UC researchers aim to address through their work. For example, UC conducts research utilizing state-managed data to inform many critical issues important to the state, including:

- **Disaster Preparedness and Response:** Studies involving communities affected by wildfires, earthquakes, and other disasters examine the psychological and social impacts of these events and inform strategies to improve resilience and recovery.
- **Public Health Initiatives:** UC researchers study the effects of air pollution, infectious diseases, and chronic health conditions on communities, with a focus on mitigating health disparities and improving access to care for underserved populations.
- **Mental Health and Behavioral Studies:** Research focuses on understanding and addressing mental health challenges such as depression, anxiety, and substance use disorders, which are prevalent across California's diverse communities.
- **Housing and Homelessness:** UC conducts studies involving individuals and families experiencing homelessness to evaluate the effectiveness of housing policies, social interventions, and support services aimed at reducing homelessness and improving quality of life.
- **Education Equity and Student Outcomes:** Researchers engage with students, educators, and families to study barriers to educational access, strategies to close achievement gaps, and programs that improve learning outcomes for marginalized communities.
- **Health Policy and Systems Research:** UC evaluates the effectiveness of state health programs like Medi-Cal, studying how these systems impact access to care, patient outcomes, and equity in healthcare delivery.
- **Workforce Development and Labor Studies:** UC researchers analyze employment conditions, job training programs, and the impact of labor policies on workers, particularly in sectors like healthcare, education, and agriculture.

### **III. Framework Extends Beyond the IPA**

CPHS has jurisdiction to review research projects that involve state-held personal information. For this role, the scope of CPHS's review is limited to the data security approvals and the criteria listed in Civil Code section 1798.24(t). But the suggested framework under consideration seemingly goes beyond data security, instead creating ethical and methodological review that is more expansive than the scope of the IPA.

In addition, it is not clear how the framework would be applied to IPA data only projects that do not need IRB review from CPHS. Without this clarification, researchers may face inconsistent or unpredictable decisions, making it harder to plan and conduct studies efficiently.

To ensure a transparent, efficient, and legally sound review process, it is essential that CPHS's role remains aligned with its statutory authority under the IPA, focusing on data security approvals rather than imposing an expanded ethical and methodological review.

### **IV. Recommendation**

To address these concerns, UC respectfully asks that CPHS not move forward with developing proposed regulations based on the proposed framework. Instead, we recommend that CPHS develop guidelines or checklists to assist researchers in understanding and implementing appropriate data protection measures in compliance with the IPA. This proactive approach would support researchers in meeting CPHS expectations without imposing duplicative reviews. UC would gladly work with CPHS to create resources that promote a clear understanding of IPA review and facilitate the progress of research.

Thank you for considering our comments on this important matter. We look forward to continued collaboration to support the advancement of research that benefits the people of California. If there is further information UC can provide on this matter that would be of help to CPHS, please do not hesitate to reach out to me at [Agnes.Balla@ucop.edu](mailto:Agnes.Balla@ucop.edu).

Sincerely,

A handwritten signature in cursive script that reads "Agnes Balla".

Agnes Balla  
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