May 6, 2024

To: CalHHS Secretary Mark Ghaly

CC: CalHHS Undersecretary Marko Mijic
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

Subject: Response to proposed changes at the Committee on the Protection of Human Subjects

Dear Secretary Ghaly:

We are a coalition of researchers and other practitioners that care deeply about the operation and effectiveness of California's government agencies and their impact on residents of the state. We are strong believers in, and practitioners of, ethical research, and want the state to reflect those values in its institutions. Most of us have used government administrative data in our research, often in partnership with state agencies, and many of us focus our research on the evaluation of public programs and policies because we believe that taxpayer dollars should be spent wisely and we should know how our programs and policies affect Californians. Our research using state data leads to better outcomes for the state and its residents.

We write today to express concerns about changes being proposed by certain members of the CalHHS Committee for the Protection of Human Subjects (CPHS). CPHS has two distinct sources of authority: (1) it is authorized to conduct institutional review board (IRB) reviews (i.e., Common Rule reviews) for CalHHS projects under its federalwide assurance; and (2) it is authorized to conduct data-security reviews under the California Information Practices Act when a state agency discloses "personal information". Each authority involves a different type of review and a different breadth of projects (though sometimes those jurisdictions overlap for a given project). At the March 1st CPHS meeting, members of the Committee proposed to expand the first authority to cover all projects falling under the second authority. Put differently, they proposed to expand CPHS's IRB authority to include all projects brought to them under the Information Practices Act.[1] These members made clear that their reason for wanting these proposed changes was to impose new individual-level consent requirements when administrative data is released by California state agencies.[2]

[1] See 1:16, 1:34, 1:40, and 2:43 of the March 1, 2024 CPHS meeting recording.

[2] See 1:17–1:35 of the March 1, 2024 CPHS meeting recording.

We write to express our deep concern about these changes and ask you to reject them. Practically speaking, these changes would effectively disable many (if not most) projects using state administrative data because individual consent is not practicable for studies with thousands or millions of subjects. The changes would also unlawfully expand CPHS's IRB jurisdiction over projects covered by existing IRBs at other research institutions, which would be redundant. This memorandum explains why the proposed changes contradict existing law and are also inadvisable on policy grounds.

Background: CPHS has two distinct sources of jurisdiction, and its jurisdiction as an institutional review board is limited to CalHHS research involving human subjects

CPHS has two distinct sources of authority. The first is CPHS's authority to act as an IRB for some research projects. That jurisdiction is circumscribed in two important ways. First, like all other IRBs, it only has purview over projects that constitute "human subjects research," as defined by federal regulations known as the "Common Rule".[3] Second, the Committee's IRB jurisdiction applies only to research projects within CalHHS.[4] This is clearly stated in the Committee's federalwide assurance (FWA #00000681)[5] which names "California Health & Human Services Agency" as the "institution" over which CPHS has authority, and lists the 13 "components" (i.e., departments) over which CalHHS has "legal authority". The Committee has no jurisdiction to review human subjects research from agencies or departments outside of CalHHS.[6] In those cases, other IRBs have jurisdiction to review projects involving human subjects research, often from the researchers' home institution.

The second source of CPHS authority is to conduct data-security reviews under the Information Practices Act (IPA). This jurisdiction applies beyond the departments of CalHHS, but the reviews themselves are more limited than IRB reviews. Namely, the reviews cover only data-security matters, and do not include a review of the study design, vulnerable groups, or general ethics. Those other topics are instead handled by the IRB with jurisdiction over the project in question (again, usually the researcher's home institution).

These two distinct areas of CPHS jurisdiction can sometimes overlap, for example when human subjects research within CalHHS (IRB authority) also involves the release of

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[3] See, e.g., 45 CFR § 46.102.

[4] We are summarizing here for simplicity. The question of what resides within CalHHS is somewhat complex, and OHRP has guidance on when institutions are "engaged" in human subjects research. See https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html. However, the contours of this jurisdiction are irrelevant to the question at hand.

[5] The federalwide assurance is available at https://hcai.ca.gov/wp-content/uploads/2020/10/Federalwide-Assurance.pdf.

[6] Applicants may request review by CPHS on a voluntary basis, but here we are discussing CPHS's jurisdiction by right.

"personal information" by a department within CalHHS (IPA authority). But in many circumstances, only one or the other applies.

Committee members are requesting to exercise IRB authority over IPA-only reviews, but that contradicts existing law

In the March 1st CPHS meeting, members Dinis, Lund, and Schaeuble[7] (henceforth, the "Requestors") requested to expand the Committee's IRB authority to apply to all applications under the IPA. Their stated intent for doing so is to expand consent requirements for the release of state data.[8] Their request contradicts clear statutory language and exceeds the authority provided to CPHS by the state legislature and the Committee's federalwide assurance. We also believe it would be redundant of existing IRB authorities and would substantially impair research using state data and thus the state's ability to learn about its own policies and programs.

The IPA does not change CPHS's IRB jurisdiction, but instead requires a separate type of review for a separate group of projects

In 1977, the California legislature passed the IPA, now encoded under Civil Code § 1798.24 (reproduced in Appendix A). The passage of the IPA did nothing to expand the Committee's IRB authority. Rather, it gave CPHS a discrete new area of work: ensuring the data security of state data released to researchers.

Under subsection (t) of the IPA, the legislature requires CPHS to review requests to make state-held "personal information" available for research purposes. The IPA applies beyond the two aforementioned limits of CPHS's IRB jurisdiction: that is, the release of state data need not be human subjects research and it need not be state data within CalHHS. For example, the IPA would apply to "personal information" disclosed by the state Departments of Education or Justice.

The IPA does not authorize CPHS to act as an IRB for projects that release state data. Rather, it mandates that CPHS provide specific "data security approvals."[9] The IPA delineates an assessment for CPHS to undertake and enumerates eight criteria that must be met in order for a project to be approved.[10] These criteria include ensuring that the researcher has "sufficient administrative, physical, and technical safeguards" to protect the data and has a "sufficient plan to destroy or return" the data upon the project's completion.[11] CPHS must also determine whether the researcher is requesting the

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[7] There may be other members on the Committee who agree with this group, but these were the ones who spoke on the record regarding this matter.

[8] See 1:17–1:35 of the March 1, 2024 CPHS meeting recording.

[9] Cal. Civil Code §§ 1798.24(t)(5) and (6).

[10] Cal. Civil Code §§ 1798.24(t)(1) and (3).

[11] Cal. Civil Code §§ 1798.24(t)(1)(A) and (B).

minimum necessary data and is enforcing minimum-necessary access to the data. The IPA explicitly states that these "data security approvals" are "for the purpose of protecting personal information held in agency databases."[12] It makes sense that the legislature gave these responsibilities to CPHS because, as one component of their IRB reviews, the Committee assesses the data security protocols of researchers.

The Requestors argue that the IPA transformed CPHS into an IRB for all projects involving the release of state data. They ask for full IRB authority (i.e., Common Rule review) over any project involving the release of "personal information" from a state entity.

Their position is contradicted by the statutory language of the IPA, which clearly delineates a prescribed review process with eight specific requirements. Had the legislature wanted to expand the applicability of the Common Rule to all projects falling under subsection (t), it could easily have done so. It need not have specifically listed the eight criteria that it wanted the Committee to consider before approval. It could have clearly stated its intention to have CPHS act as an IRB for all projects involving state data. In doing so, it could have moved the CPHS out from under CalHHS and into some other part of the executive branch. It also could have included in the IPA other criteria that relate to ethics, consent, or vulnerable groups – all components of normal IRB review. But the IPA did none of those things. It merely carved out a new task for CPHS that is more limited than its usual IRB reviews and applies outside of its customary IRB jurisdiction.

Requestors argue that the IPA acts as a floor rather than a ceiling, which is true, but only for purposes of assessing data security

The Requestors argue that the IPA sets a floor to their review and not a ceiling. They point to language in subsection (t)(3) which states that the listed criteria are a "minimum":

> "The CPHS . . . shall, at a minimum, accomplish all of the following as part of its review and approval of the research project for the purpose of protecting personal information held in agency databases . . ."[13]

Requestors argue that the "at a minimum" language should allow them to apply the Common Rule (i.e., full IRB review) to any project seeking only IPA approval. We respectfully disagree, for two reasons.

First, their argument ignores the plain language of the statute. At the end of the sentence in question, the IPA states that CPHS's review is only "for the purpose of protecting personal information held in agency databases."[14] So while it is true that the IPA sets only a minimum necessary review, it also circumscribes that review to the purpose of data

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[12] Cal. Civil Code §§ 1798.24(t)(5), (6), and (3).

[13] Cal. Civil Code § 1798.24(t)(3).

[14] Id.

security. In other words, it sets a floor, not a ceiling, but it also places firm walls around the scope of the Committee's review. This is reinforced in two later subsections of the IPA, which describe CPHS's review as giving "data security approvals" and enforcing "data security requirements."[15] That language suggests that the legislature intended CPHS to ensure the data's security but not to undertake a more expansive IRB review under the Common Rule.

The eight criteria listed by the legislature are further evidence that the review intended by the IPA must be limited to data security matters. Those criteria, listed in full in Appendix A, ensure that the researcher has a data destruction plan, has implemented "administrative, physical, and technical safeguards", is using the minimum necessary information, is giving access to the minimum necessary people, and does not unnecessarily transmit social security numbers.[16] These requirements are standard aspects of ensuring data security but none of them pertain to the substantial study-design and ethical aspects of normal IRB review. Under the canon of statutory construction *ejusdem generis* (Latin for "of the same kind"), when statutes provide enumerated examples and then a more general term, the general term is interpreted to be limited to the same category as the examples. In this situation, the enumerated criteria all pertain to data security, and any additional review that CPHS undertakes would need to be confined to data security concerns as well.

Projects submitted for IPA review are already subject to review by other IRBs

The second reason that Requestors' interpretation of the IPA is too expansive is that it would lead to absurd and redundant results. The proposed changes ignore the fact that projects submitted for IPA review are already subject to the review of other IRBs. Expanding CPHS's IRB authority to cover these projects would be redundant.

Every research institution that receives any federal funding, including nearly all universities, must either run their own IRB or contract with an external IRB to review human subjects research (whether or not the research itself receives federal funding). This is a vital role for each research institution and is an essential component of every research project.

Thus, projects submitted for IPA review are already subject to IRB review at the researcher's home institution. For example, if a UCLA research project used "personal information" from the state's Department of Justice, then that project would need to get three approvals: (1) project approval from the Department of Justice; (2) IRB approval from UCLA, and (3) IPA approval from CPHS.

Under Requestors' interpretation, the Committee – which sits within CalHHS – could overrule the decisions of the UCLA IRB and the Department of Justice, both of which have

[15] Cal. Civil Code §§ 1798.24(t)(5) and (6).

[16] Cal. Civil Code §§ 1798.24(t)(1)(B), (1)(A), (3)(A), (3)(B), and (3)(C).

clear jurisdiction over their respective areas. UCLA IRB's federalwide assurance gives it IRB authority over human subjects research conducted by UCLA faculty. And the Department of Justice has clear authority to decide which projects to approve to use its data.[17] Why would a Committee sitting within CalHHS have purview to reverse the decisions of the university IRB and the Department of Justice? The legislature could not have intended CPHS to have such broad reach over other departments and agencies or to contradict the federally assigned jurisdiction of other IRBs. Rather, when the legislature enacted the IPA, it clearly intended to circumscribe CPHS's new authorities to enforcing specific "data security requirements".[18]

The applicability of the Common Rule to data-only projects is a red herring; it applies only when CPHS is acting as an IRB

During the March 1st meeting, the Committee considered a separate legal issue regarding the Common Rule's coverage of "data-only" projects, meaning projects that involve no contact (direct or indirect) with living individuals (we use the Requestors' language here for convenience, although "data-only" is not a fully accurate summary of the law). An example of a "data-only" project is one in which a researcher is using previously existing data on enrollment and assessments from a school district but where the researcher will not be contacting the students represented in that data.

The attendees at the March 1st meeting seemed to think that this issue is relevant to the Requestors' request for additional authority, but we think it is a red herring. The gist of Requestors' argument is that (1) the Common Rule covers some "data-only" projects; (2) IPA reviews are usually "data-only" projects; so therefore (3) CPHS should always be able to review IPA-only projects under the Common Rule. The first two parts of Requestors' argument are true, but the third part does not logically follow. Just because the Common Rule sometimes covers "data-only" projects does that mean that all "data-only" projects are reviewable under the Common Rule.

For their first point, the Requestors cite guidance[19] from the federal Office for Human Research Protections (OHRP) regarding projects that involve existing administrative data.[20] The guidance cites federal Health and Human Services regulations that define "human subjects" to include research where the investigator "uses . . . identifiable private information".[21] By citing this guidance, the Requestors sought to clarify that "data-only" projects fall within CPHS's IRB jurisdiction. They apparently wished to contradict a decision tree provided by CPHS counsel that suggested that "data-only" projects do not fall within CPHS's IRB jurisdiction.

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[17] See Cal. Penal Code § 13202.

[18] Cal. Civil Code §§ 1798.24(t)(5) and (6).

[19] See https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c1.

[20] See 0:24 and 2:19 of the March 1, 2024 CPHS meeting recording.

[21] 45 CFR 46.102(e)(1)(ii) and (e)(4)–(6).

We agree with Requestors that "data-only" projects may meet the definition of "human subjects" if the data includes "identifiable private information" as defined in federal regulations.[22] We also agree that "data-only" projects may therefore be reviewed by CPHS *when it is acting as an IRB*. However, the fact that CPHS has authority to review "data-only" projects under the Common Rule where it *has* IRB jurisdiction does not permit them to review "data-only" projects under the Common Rule where it *does not have* IRB jurisdiction. As mentioned above, CPHS has two clear limits to their IRB jurisdiction: (1) it must be "human subjects research" and (2) it must be a project within CalHHS. Requestors argument here merely demonstrates that some "data-only" projects can be "human subjects research." But if the project falls outside of CalHHS, and therefore outside the IRB jurisdiction of CPHS, then the Committee has no authority to review it under the Common Rule.[23] The only reason such a project comes to CPHS is because of the IPA; it would otherwise be reviewed by a different IRB or not be reviewed at all (if it wasn't human subjects research). When researchers submit their projects for approval to CPHS, they must clearly state whether they are requesting IPA review, Common Rule review, or both. When they are requesting IPA-only review, and when the project does not otherwise fall within the IRB jurisdiction of CPHS, then the Committee has no authority to review it under the Common Rule. The fact that the project is "data-only" is irrelevant to that analysis. In fact, the same would be true if an IPA-only project involved direct contact with human subjects: if the project falls outside of CalHHS, it falls outside of the Committee's IRB jurisdiction.

The Requestors' proposed change is also inadvisable on policy grounds

As explained above, Requestors' proposed change is legally impermissible, and we urge the Secretary to reject it on those grounds alone.

However, we also think it is important to explain the negative policy implications of the Requestors' proposal because they may not be immediately obvious and yet are quite serious. Put simply, it would disable important research using the state's administrative data and roll back years of progress that CalHHS and other state agencies have made in improving data sharing across state agencies.

CalHHS has been a leader in the use of administrative data for policy and research purposes for several years. It was the first agency to require its departments to sign a joint data-use agreement, a process that was later replicated by other agencies. It also undertook a "record reconciliation" process to link records across several programs within CalHHS, so that policymakers could understand the cumulative impact of proposed policy changes on a given household. Later, CalHHS launched the Center for Data Insights and

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[22] Id.

[23] Applicants may request, on an optional basis, that CPHS review a project that would generally fall outside the Committee's jurisdiction, but that is not at issue here.

Innovation and pioneered the Agency Data Hub, which makes the linking and sharing of data within government and with researchers much easier than before. All of this important work was undertaken with a firm belief that government administrative data can provide powerful insights that can improve the effectiveness of government programs and, in turn, improve the lives of Californians.

The Requestors' proposal would seek to undo the important work that CalHHS has undertaken. On its face, Requestors are simply seeking to clarify the Committee's jurisdiction. But *the reason* Requestors seek this new authority is because they want to require individual consent for research projects that re-use existing state administrative data. This intent was stated in the March 1st meeting[24] and at prior CPHS meetings as well.[25]

We will try to do justice to Requestors' rationale for requiring such consent, since it is based in values around individual privacy that we also share. Requestors believe that individuals who provide data to government agencies often do so without adequate consent. For example, when someone goes to the emergency department, they are unlikely to read the fine print in a privacy policy explaining which future uses of their data are authorized. Moreover, some information is recorded without any consent at all (e.g., at birth or upon arrest), and some information is collected without mentioning the future prospect that individual data may be used in research studies. Requestors are especially concerned about projects that link data between different datasets, because they believe that individuals could not have been plausibly aware that such linkages would occur and therefore could not have given informed consent.

We agree that when individuals give their information to government agencies they usually have very little sense of how that data will be used in the future. However, we disagree with Requestors' contention that CPHS has the authority to fix this issue. We also disagree with them about the right policy resolution: Requestors believe that the lack of initial consent should be cured, later, with individual consent (at least in some cases). It is our contention that such consent would render impossible all but a few projects using government administrative data. The sheer cost of reaching out to thousands or millions of California residents would be astronomical,[26] and even if one could muster the financing, the resulting selection bias would scuttle most research projects.[27]

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[24] See 1:17–1:40 of the March 1, 2024 CPHS meeting recording.

[25] See, for example, 0:51–1:02, 1:06–1:08, and 1:43–1:45 of the June 2023 CPHS meeting recording.

[26] Consider an example project in which SNAP (i.e., food assistance) records were used to determine who was eligible for the California Earned Income Tax Credit. Getting individual consent from California's 4.6 million SNAP participants would be cost prohibitive.

[27] Those who opt-in are likely to be different from those who do not in ways that would distort the sample and the research results.

We are not the only ones to disagree with Requestors' proposed resolution: the federal and state legislatures do as well. Policymakers have long appreciated the fact that users of government services are unlikely to have the opportunity for informed consent at the time their data is collected. Their policy resolution has been to put in place dozens of laws and regulations protecting government administrative data from misuse. The IPA is one such statute, but there are several more.[28] These laws forbid the disclosure of most data collected by government agencies, except in specific limited circumstances. For example, one such law forbids disclosure of the state's tax records, but allows an exception for sharing with the Department of Health Care Services for the purpose of verifying income eligibility for Medi-Cal.[29] This exception is permitted because the legislature has weighed its pros and cons and has come to the conclusion that such sharing is warranted on policy grounds. Such policy decisions are the appropriate role of legislators.

In most data-disclosure laws, legislators have included an exemption (to a greater or lesser extent) for research.[30] Ostensibly these research exemptions exist because the legislature concluded that research creates value for society and that government administrative data is a vital source of data for such research. One may reasonably disagree with this policy decision, for example on the grounds that it does not value individual privacy strongly enough. This, it seems, is the Requestor's position. But holding this policy opinion does not grant them the legal authority to carry it out. The Requestors' proposal would effectively allow CPHS to second guess the legislature's policy decisions, but they have no such authority nor are they the appropriate body to make such determinations.

On policy grounds, we believe Requestors' desire to require individual consent for studies that use California administrative data would be disastrous. In practice, it would disable hundreds of studies from happening each year. Much of this research is studying the impact of government policies and programs, so that Californians can have a more effective government. Other such research seeks to improve the healthcare system or our systems of public education. A new consent requirement for use of administrative data would wipe out these considerable benefits. It would, in essence, curtail any rigorous evaluation of state policies and programs on individual outcomes.

We think Requestors' position also exaggerates the potential costs to individual privacy. We are strong believers in individual privacy and in protecting the identities of people represented in data that we use for research purposes. Even when anonymized person-

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[28] See, for example, Cal. Unemployment Insurance Code § 1094 protecting earnings records, Cal. Welfare and Institutions Code § 17006 protecting social services records, Cal. Health and Safety Code § 11845.5 protecting substance abuse records, Cal. Penal Code § 13202 protecting criminal justice records, and Cal. Revenue and Tax Code §§ 19542–19572 protecting state tax records.

[29] See Revenue and Taxation Code § 19548.5.

[30] See, for example, 20 U.S.C. § 1232g(b)(1)(F) allowing research using education data, Cal. Education Code § 10862 allowing research using the Cradle-to-Career data system, Cal. Penal Code § 13202 allowing research using criminal justice data, and Cal. Health and Safety Code § 103206 allowing research using CalHHS data.

level data is required for a research project, our goal – always – is to glean *aggregated* insights that can apply to broad policies and programs. We know these core values are shared by the CalHHS agency leadership because they have worked so hard to put CalHHS data to good research use. Existing laws and regulations already do a good job of ensuring that state administrative data is shared in a fashion that minimizes potential harms to individuals.[31] Most data are anonymized before they are disclosed to researchers so that no identifying information (e.g., names, social security numbers) is attached. When a study requires data to include identifying information, statues and regulations require strict data-security protocols to be in place.

The IPA is exactly one such statute that ensures "data security requirements" are in place.[32] CPHS has been tasked with providing such "data security approvals" by reviewing eight criteria,[33] but Requestors want to transform that limited authority into something much more expansive. If such additional authority is granted, it would disrupt the progress that CalHHS – and California state government more broadly – has made in leveraging administrative data to generate new evidence.

CPHS – like all IRBs – is largely unaccountable, so CalHHS should regularly review the conduct and composition of CPHS

In this final section, we mention an important note about IRBs in general, which is that they are largely unaccountable. This is true of all IRBs, including the CalHHS CPHS. For example, if a project is rejected by CPHS, there is no other body to which a researcher may appeal.[34] This independence is part of the strength of IRBs – but it can also be a risk.

There are various historical examples where this lack of accountability has caused problems, and this is something that universities (and the federal government) have had to deal with from time to time.[35] Because research is existential for universities, they tend to

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[31] In fact, the thrust of most recent policy efforts – at both the state and federal levels – is to make administrative data *more* available for research. Such is the impetus behind California's Cradle-to-Career data system (Cal. Education Code § 10860–10874) and behind the federal Foundations for Evidence-Based Policymaking Act of 2018 (5 U.S.C. § 311–15).

[32] Cal. Civil Code §§ 1798.24(t)(5) and (6).

[33] Cal. Civil Code §§ 1798.24(t)(1), (3), (5), and (6).

[34] The CPHS Policies and Procedures (p. 31) allow limited appeal back to the Committee itself, but not to any other body.

[35] See, for example, Simon Whitney, *From Oversight to Overkill: Inside the Broken System That Blocks Medical Breakthroughs--And How We Can Fix It* (Rivertown Books, 2023); Ryan Briggs, *The Abject Failure of IRBs: Ethics-review systems have become exercises in absurdity and unpredictability* (Chronicle of Higher Education, March 23, 2022)*;* Sarah Babb, *Regulating Human Research: IRBs from Peer Review to Compliance Bureaucracy* (Stanford University Press, 2020); Carl Schneider, *The Censor's Hand: The Misregulation of Human-Subject Research* (MIT Press, 2015); and Patricia Cohen, *As Ethics Panels Expand Grip, No Field Is Off Limits* (New York Times, Feb. 28, 2007).

closely monitor the conduct and composition of their IRBs, to ensure that they are appropriately balancing the principles in the Belmont Report and the Common Rule.

There are similar risks for all IRBs, and the CPHS is no exception. As a result, the CalHHS Secretary has a similar responsibility to ensure the appropriate conduct and composition of CPHS and to ensure that it is not exceeding its jurisdictional bounds.

In light of this, we were disturbed to learn that Committee members may have contradicted the clear advice of CPHS counsel and may have made decisions that exceeded the bounds of their authority.[36] That would be concerning behavior for any government official, but especially so for ones charged with ethical oversight and whose decisions are essentially unappealable. We think this conduct deserves the Secretary's attention and, more generally, we believe that regular attention to the Committee's composition is warranted.

Thank you for your consideration in this matter. If you should have any questions, please feel free to reach out to the main author at evanbwhite@berkeley.edu.

Sincerely,

Evan White, Esq.
Executive Director, California Policy Lab, UC Berkeley

[36] See 1:55 of the March 1, 2024 CPHS meeting recording and 1:27–1:57 of the June 2023 CPHS meeting recording.

Appendix A – Information Practices Act

Relevant sections only

California Civil Code 1798.24

An agency shall not disclose any personal information in a manner that would link the information disclosed to the individual to whom it pertains unless the information is disclosed, as follows:

…

(t) (1) To the University of California, a nonprofit educational institution, an established nonprofit research institution performing health or social services research, the Cradle-to-Career Data System, for purposes consistent with the creation and execution of the Cradle-to-Career Data System Act pursuant to Article 2 (commencing with Section 10860) of Chapter 8.5 of Part 7 of Division 1 of Title 1 of the Education Code, or, in the case of education-related data, another nonprofit entity, conducting scientific research, if the request for information is approved by the Committee for the Protection of Human Subjects (CPHS) for the California Health and Human Services Agency (CHHSA) or an institutional review board, as authorized in paragraphs (5) and (6). The approval shall include a review and determination that all the following criteria have been satisfied:

> (A) The researcher has provided a plan sufficient to protect personal information from improper use and disclosures, including sufficient administrative, physical, and technical safeguards to protect personal information from reasonable anticipated threats to the security or confidentiality of the information.
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> (B) The researcher has provided a sufficient plan to destroy or return all personal information as soon as it is no longer needed for the research project, unless the researcher has demonstrated an ongoing need for the personal information for the research project and has provided a long-term plan sufficient to protect the confidentiality of that information.
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> (C) The researcher has provided sufficient written assurances that the personal information will not be reused or disclosed to any other person or entity, or used in any manner, not approved in the research protocol, except as required by law or for authorized oversight of the research project.

(2) The CPHS shall enter into a written agreement with the Office of Cradle-to-Career Data, as defined in Section 10862 of the Education Code, to assist the managing entity of that office in its role as the institutional review board for the Cradle-to-Career Data System.

(3) The CPHS or institutional review board shall, at a minimum, accomplish all of the following as part of its review and approval of the research project for the purpose of protecting personal information held in agency databases:

(A) Determine whether the requested personal information is needed to conduct the research.

(B) Permit access to personal information only if it is needed for the research project.

(C) Permit access only to the minimum necessary personal information needed for the research project.

(D) Require the assignment of unique subject codes that are not derived from personal information in lieu of social security numbers if the research can still be conducted without social security numbers.

(E) If feasible, and if cost, time, and technical expertise permit, require the agency to conduct a portion of the data processing for the researcher to minimize the release of personal information.

(4) Reasonable costs to the agency associated with the agency's process of protecting personal information under the conditions of CPHS approval may be billed to the researcher, including, but not limited to, the agency's costs for conducting a portion of the data processing for the researcher, removing personal information, encrypting or otherwise securing personal information, or assigning subject codes.

(5) The CPHS may enter into written agreements to enable other institutional review boards to provide the data security approvals required by this subdivision, if the data security requirements set forth in this subdivision are satisfied.

(6) Pursuant to paragraph (5), the CPHS shall enter into a written agreement with the institutional review board established pursuant to former Section 49079.6 of the Education Code. The agreement shall authorize, commencing July 1, 2010, or the date upon which the written agreement is executed, whichever is later, that board to provide the data security approvals required by this subdivision, if the data security requirements set forth in this subdivision and the act specified in subdivision (a) of Section 49079.5 of the Education Code are satisfied.