To: CPHS Board Members
From: CPHS Administrator; CPHS Chair; CPHS Vice-Chair
Date: August 26, 2026
Subject: Revised CPHS Policies & Procedures Manual — High-Level Overview

Purpose: This memorandum provides a high-level overview of proposed updates to the California Health & Human Services Agency (CalHHS) Committee for the Protection of Human Subjects (CPHS) Policies & Procedures (P&P) Manual. The updates modernize the manual, clarify scope and processes, and align CPHS operations with applicable federal and state requirements. This summary is informational and the proposed revisions do not change CPHS statutory authorities, responsibilities, or the standards applied to review.

About CPHS: CPHS serves as CalHHS's Institutional Review Board (IRB), responsible for the protection of human subjects in research in which CalHHS is engaged, ensuring that such research is ethically conducted, minimizes risk, and complies with applicable federal and state requirements, including the Common Rule (45 CFR 46) and relevant FDA regulations (21 CFR Parts 50, 56, 312, and 812). CPHS also reviews requests for the release of identifiable state data for research under the California Information Practices Act (IPA; Civ. Code § 1798.24(t)).

Summary of Proposed Updates at a Glance:

- Clarifies when CalHHS is "engaged" in human subjects research and how that determines CPHS IRB oversight versus IPA-only review.
- Aligns submission pathways with federal categories, enabling consistent use of expedited review for eligible minimal-risk research.
- Transitions eligible minimal-risk studies from annual Continuing Reviews to an Annual Administrative Check-In consistent with federal expectations.
- Combines member expectations with institutional support: defines roles, training, appointment/renewal, attendance, conflict-of-interest standards, and recognizes the need for protected time to prepare and participate in CPHS activities.
- Establishes a clear oversight and accountability framework for non-federally funded research under CPHS authority.
- Standardizes documentation, operational procedures, and key definitions across the manual.

1. **Engagement and Scope of CPHS Oversight.** The proposed revisions clarify that CPHS conducts IRB review when CalHHS is engaged in human subjects research in alignment

with guidance from the Office for Human Research Protections (OHRP)[1]. Engagement is determined by objective criteria consistent with published federal guidance and includes CalHHS conducting or directing research activities (including through research contracts), participating in consent procedures, intervening or interacting with participants for research purposes, or obtaining identifiable private information for research purposes.

Releasing identifiable state administrative data for secondary analysis, by itself, does not constitute CalHHS engagement. A narrow exception applies when identifiable information is used to contact individuals for recruitment; in that circumstance, CPHS would review the limited scope of the recruitment, screening, and consent activities that create engagement, while other research procedures remain under the researching institution's IRB.

These clarifications are intended to provide consistent pathways for IRB review and for IPA-governed data requests, ensuring that CPHS oversight is consistently applied.

2. **Submission Pathways and Expedited Review.** The manual updates align CPHS practice with federal expedited review categories for eligible minimal-risk research and clarify exclusions. Standardized reviewer tools and checklists will support consistent application of regulatory criteria across review types (exempt, expedited, and convened). Use of expedited review is an IRB process conducted by designated, experienced members and applies the same approval standards as convened review.

3. **Annual Administrative Check-In.** For eligible minimal-risk studies, the revised manual replaces routine annual Continuing Reviews with an Annual Administrative Check-In conducted by CPHS administrative staff. This maintains an annual compliance touchpoint and aligns with federal expectations for minimal-risk research. When continuing review is required, it is conducted by the IRB (a member or the convened board, as applicable).

4. **Member Expectations and Institutional Support.** The revised manual describes member roles and responsibilities, training expectations, conflict-of-interest standards, and in-person attendance requirements consistent with quorum and open-meeting laws. It formalizes appointment and renewal on a defined cycle, with expectations that promote preparedness, participation, and respectful deliberation. Recognizing the time required for rigorous review and participation, the manual identifies proposed mechanisms, such as protected work time for CalHHS employees appointed to CPHS, to prepare for and participate in CPHS activities, subject to Agency policies and decision-

[1] See 2008 and 2011 OHRP guidance.

making. Eligibility for alternates is broadened to include individuals who meet training and conflict-of-interest requirements, enhancing flexibility to maintain quorum and continuity.

5. **Oversight, Accountability, and Enforcement for Non-Federally Funded Research.** The revised manual clarifies investigator responsibilities, Responsible Official oversight, and CPHS's authority to make determinations and require corrective actions when necessary to protect participants and uphold CPHS requirements. The CalHHS Secretary is responsible for enforcing CPHS determinations, including sanctioning investigators who violate CPHS requirements, federal regulations, or the rights and welfare of human subjects. The manual also standardizes processes for addressing reportable events, noncompliance, and required notifications across funding sources.

Additional Notable Updates:

- Integration of applicable FDA regulatory frameworks, including device risk determinations and emergency use.
- Expanded definitions and glossary (e.g., engagement, minimal risk, secondary research, vulnerable populations).
- Enhanced procedures for exempt research, informed consent (including non-English consent), recruitment, advertisements, and compensation.
- Policies for vulnerable populations consistent with federal subparts.
- Records management and retention standards for IRB documentation.
- High-level data security expectations for IPA-governed research, including secure storage, access controls, and incident reporting.
- Procedures for complaints and appeals, with transparent documentation of resolution steps.

Closing: The proposed updates are designed to clarify CPHS processes, promote consistency, and support timely, high-quality reviews. They do not change the standards applied to protect the rights and welfare of research participants or CPHS's authority within its scope of oversight.