CPHS Policies and Procedures Revisions – Overview of Key Proposed Changes

Purpose of Today's Briefing

Not a review of the policy manual line by line.

Today we will:

- Explain the major proposed changes in the revised P&P
- Describe the regulatory or operational basis for those changes
- Illustrate how member review responsibilities may change
- Answer clarification questions
- Identify topics requiring additional education before implementation

Today we will not:

- Ask members to vote on or approve the revised P&P
- Poll members regarding support or opposition
- Seek consensus on policy provisions
- Deliberate toward a collective Board position
- Communicate one member's views to other members through subsequent briefing sessions

Formal Board deliberation or action, if required, will occur only through an appropriately noticed CPHS meeting.

Executive Summary: What the Revisions Accomplish

Align

Federal regulations and guidance

Clarify

Authorities and responsibilities

Standardize

Review and documentation expectations

Address

Compliance gaps identified through external review and operations

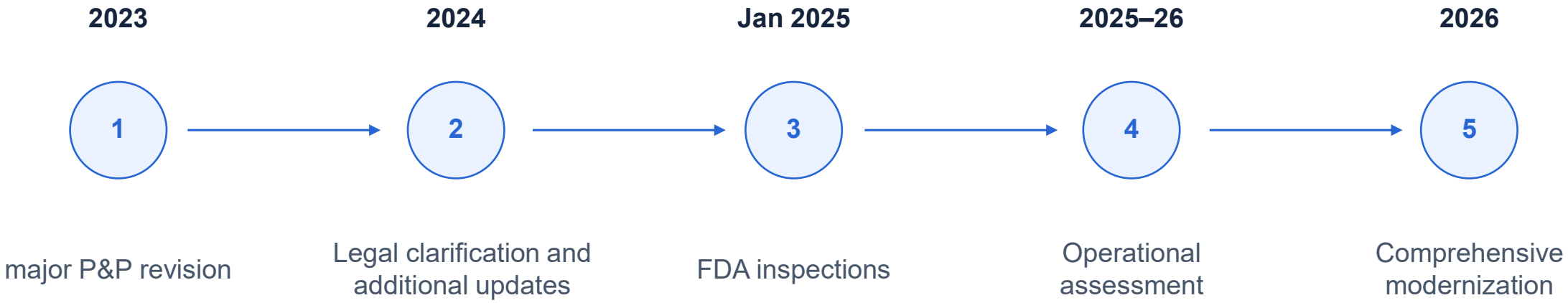
Operationalize

Processes where policies were silent

What members should expect:

- New reviewer tools/checklists
- More explicit regulatory determinations
- Some work shifting from convened review to designated-member review
- Additional training before implementation

What is Driving the Revision?



The revision is a modernization effort responding to audit inspections, operational inconsistency, and missing procedural detail.

The objective is not to change CPHS's protective mission; it is to provide the policy detail and decision structures needed to carry out that mission consistently.

Where the Existing Manual Needed More Specificity

The proposed revision strengthens the manual where practice depended on interpretation rather than explicit policy, procedure, or documentation requirements.

Review criteria

- Approval criteria operationalized
- More consistent reviewer checklists
- Clearer basis for required changes

Regulatory topics

- UAP / SNC / CNC definitions
- FDA, HIPAA, and reliance/sIRB
- Vulnerable population safeguards

Board operations

- Reviewer roles and expectations
- Motions, voting, and minutes
- Member training and attendance

Common objective → **Consistent review + defensible documentation** → **Implementation readiness**

Clarifying CPHS jurisdiction and review capacity

The revised policy separates three related—but distinct—questions that have historically been blurred.

1 Research requiring CPHS IRB review

CalHHS is engaged in the research → CPHS acts as an IRB

2 IPA-only review

State-held identifiable information is released, but CalHHS is not engaged → CPHS acts under IPA authority, not as the reviewing IRB

IPA-only review is not IRB review; federal sIRB mandates therefore do not apply to CPHS's IPA-only function.

3 Recruitment-data engagement

State identifiable information is released to contact potential participants → CPHS conducts a **limited-scope IRB review** of:

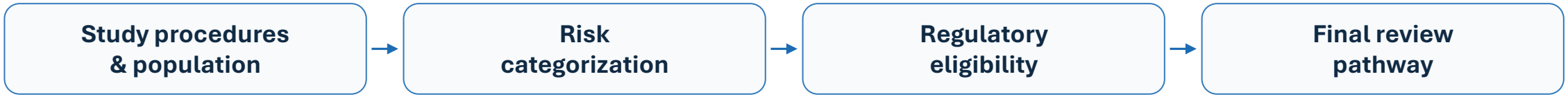
- Recruitment
- Screening
- Informed consent activities

The remainder of the research is outside CPHS's IRB review under this engagement criterion, unless another CalHHS engagement criterion or an independent statutory or regulatory review authority applies.

For example, CPHS may retain separate review responsibilities under the vital statistics statutes, HIPAA Privacy Board authority, or other applicable California law.

Review Pathway: Procedures + Risk + Regulatory Eligibility

The change is not “minimal risk = expedited.” The pathway is determined by what the study does, who is included, the risk level, and the applicable regulatory category.



Current practice emphasis

Human interaction often routes to full board

Proposed emphasis

Procedure-based risk + regulatory category drive pathway

Example

Anonymous adult interview study → assess risk and procedures → consider exemption → if not exempt, consider expedited Category 7 → convened review only if criteria/context warrant.

Important: expedited review is IRB review. It does not apply a reduced approval standard.

Approval Criteria: What CPHS Is Actually Determining

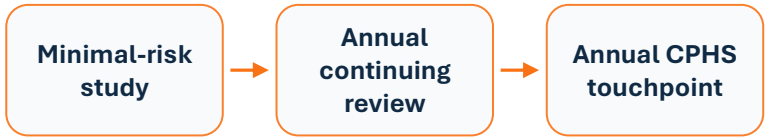
When serving as an IRB, the central review question is whether CPHS can document that the applicable criteria for approval are satisfied.



Ongoing Oversight: Continuing Review and Administrative Check-Ins

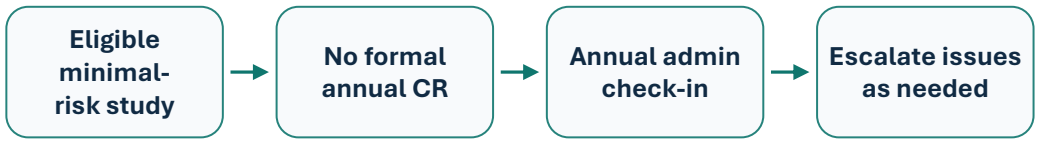
The revised framework distinguishes formal IRB continuing review from routine administrative monitoring.

Current approach



Under the revised framework, formal continuing review and administrative monitoring are treated as distinct processes.

Revised approach



The annual check-in preserves an ongoing compliance touchpoint without requiring a formal IRB approval action

Formal continuing review still applies when required

Reviewed by a designated IRB member or the convened Board • Applicable approval criteria reassessed • Review interval documented

The revised approach maintains ongoing oversight while matching the type of review to the applicable regulatory requirement.

Reportable Events: From AE Focus to Required Determinations

The proposed revised framework moves from categorizing events to documenting the IRB determinations that drive corrective action and reporting.

Current emphasis

Adverse Event (AE)/ Serious Adverse Event (SAE) reported

↓

Board discussion or action

Revised framework

Event or information → **Staff / Chair screening** → **IRB determination** → **Action / CAPA / reporting**

- **Unanticipated Problem (UAP)?**
- **Serious Noncompliance (SNC)?**
- **Unanticipated Adverse Device Effect (UADE)?**
- **Continuing Noncompliance (CNC)?**

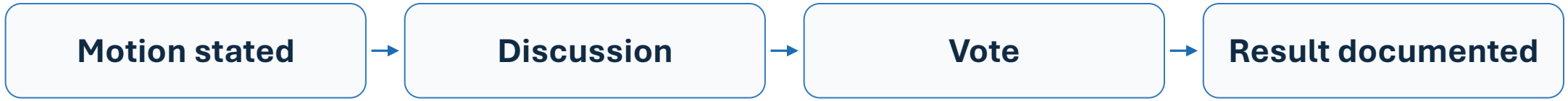
Teaching points

- **An SAE is not automatically a UAP**
- **A UAP does not have to be an AE**
- **Positive determinations drive reporting obligations**

This change is a core compliance improvement: the record must show the determination, not just that the event was acknowledged.

Board Motions and Voting: What a Vote Means

The revised manual should help members distinguish the protocol, the motion, the vote, and the documented determination.



1. Vote on the specific motion

Members vote on the specific motion or determination before the Board, applying the same regulatory criteria and standards consistently across protocols.

2. Tie motion to findings

Motions should correspond to required actions or findings: approve, approve with conditions, defer, disapprove, UAP, SNC, CNC, device risk, waiver, etc.

3. Distinguish abstention / recusal

Abstention means a member remains present but does not vote yes/no. Recusal means the member does not participate in that item due to conflict.

“What motion is actually before the Board, and what specific regulatory findings would support that motion?”

What Changes for Members

Roles, tools, and review responsibilities become more explicit so members can apply standards consistently across submission types.

Member experience

Before — Expectations embedded across policy and practice

After — Roles, timelines, tools, and determinations stated directly

Goal: clarify what members review, determine, and document.

Training

Required education and topic-specific orientation before implementation

Preparation

Clearer expectations to review assigned materials and use reviewer tools

Individual review

Designated members may conduct expedited reviews using standardized criteria

Board operations

More explicit motion, voting, quorum, abstention, and documentation practices

Appointments

Renewal cycle and broader pathway for trained alternates

Questions, Continued Education, and Next Steps

These briefings are designed to inform members and clarify implementation—not to poll support, deliberate toward consensus, or develop a collective Board position outside a noticed meeting.

Questions we can address today

- What does this provision mean?
- How would this work in practice?
- Which criteria would apply?
- Where is this addressed in the manual?

Not part of these briefings

- Poll member positions
- Seek support or opposition
- Develop consensus
- Carry one member's view into another session

What happens next

- Public Board meeting to discuss Board and public feedback
- CPHS staff will prepare packet for review by CalHHS Secretary, including proposed policies and feedback, and CalHHS Secretary will determine whether to approve

Formal Board deliberation or action, if required, will occur only through an appropriately noticed CPHS meeting.