

Proposed CPHS Fees

AUGUST 2, 2024

MEETING OF THE CalHHS COMMITTEE FOR THE PROTECTION OF HUMAN
SUBJECTS

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Statutory Authority

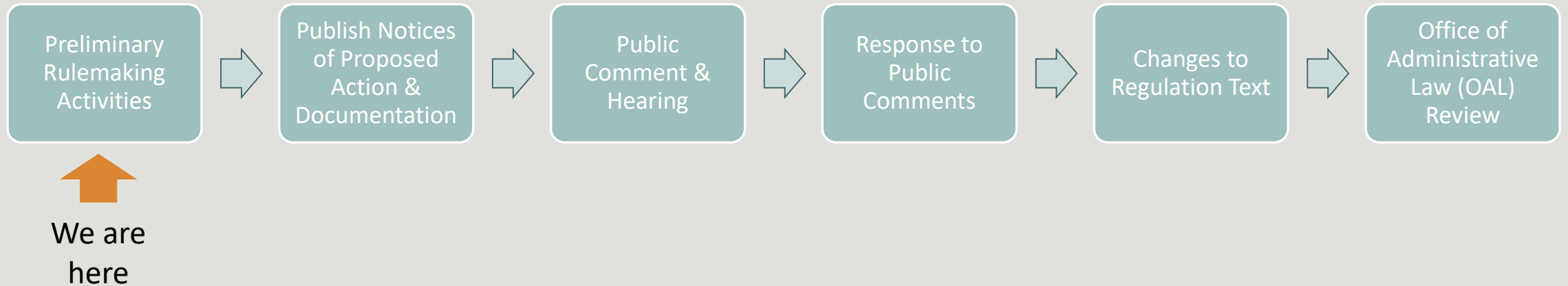
California Health and Safety Code, Division 109, Section 130207(f):

“The center may collect fee-for-service payments from a nonstate entity for services provided to the nonstate entity by the State Committee for the Protection of Human Subjects.”

Why Regulations?

California Health and Safety Code, Division 109, Section 130207(f) does not establish the fee schedules.

To define the fee schedule, we will need to follow the Regulations process.



Preliminary Rulemaking Activities

Market Research & Workload Analysis

Preliminary feedback from CPHS Chairs

Feedback from CPHS Full Committee  We are here

Refinement based on feedback

Endorsement by CPHS Full Committee

Market Research

Researched 10 IRBs' fee structures

UC Davis

UCLA

Northwestern
University

Penn State
University

UCSF Affiliated
Institutions

UCSF Private
Industry

Boston
University
Medical Campus

Oregon Health &
Science
University

University of
Arizona

University of
Nevada, Reno

Proposed Fees

Application/Review Types	Proposed Fees
Initial Submission - Full Board Review	\$3,500.00
Initial Submission - Expedited Review**	\$2,100.00
Initial Submission - Not Research/Exempt Review	\$500.00
Continuing Review - Full Board	\$1,200.00
Continuing Review - Expedited Review**	\$1,000.00
Amendment - Full Board Review	\$1,400.00
Amendment - Major Change Expedited Review	\$1,200.00
Amendment - Minor Change Expedited Review	\$0.00
Closure Report	\$0.00
Adverse Event	\$0.00

** Expedited reviews may require a Full Board review due to Committee Member's discretion and may impact the fee's according to the CPHS fee schedule.

Revenue Projections

Projected Revenue by Review Type Based on Proposed Fee Schedule and Number of Research Requests in 2023.

	Full Board Review	Expedited Review	Exempt Review	CR Applications*	Full Board Amendments	Amendments Major Change	Total
2023	20	103	19	746	2	41	931
Fee	\$3,500	\$2,100	\$500	\$1,000	\$1,400	\$1,200	
Estimated Revenue	\$70,000	\$216,300	\$9,500	\$746,000	\$2,800	\$49,200	\$1,093,800

*The Continuing Review (CR) data includes all research projects. There is no data in IRBManager to separate CR applications by State and non-state entities. State entities are not subject to fees.

Workload Analysis

Considerations included additional resources (staff, third party billing company fees, etc.) needed to process fees.

Estimated costs are \$600,000.

Projected Revenue	\$1,093,800
Projected Costs	\$600,000
Remaining Funds	\$493,800

Proposed Regulations

Who:

Only non-state entities are charged fees.

The projects must meet criteria for CPHS review.

When:

January 1, 2026

Proposed Regulations

Escalation: Expedited escalated to Full Board Review will need to pay the difference between the fees.

Continuing Reviews: If a project expires due to Committee inaction, they are not subject to additional fees.

Amendments: Fees are charged for substantial changes.

Payment: Payment must be made prior to decision by the Committee.

Changing fees: Permissible once every 3 years, by Committee vote. No more than 10% or \$500, whichever is lower.

Permissible Uses of Funds Generated

Fees can only be used to administer, manage, and support the Committee. For example:

- Operational costs (e.g., admin staff, translation services, etc.)
- Expert consultation
- Platform improvements

Initial Feedback

- Fee waivers for Graduate Students.
- Grandfathering in currently active studies.