Sutter Health Institutional Review Board
2121 N. California Blvd., Suite 310, Walnut Creek, CA 94596
SHIRB@sutterhealth.org

Sutter Health Institutional Review Board (SHIRB)

JANUARY 2022

FEE SCHEDULE*	
Category of Review	**Fee**
INITIAL REVIEW SUBMISSION:	
New study (including Humanitarian Use Device [HUD] applications and Expanded Access Protocols [EAP])	**$3,500.00**
ONGOING REVIEWS OF APPROVED PROTOCOL:	
Continuing Review/Progress Report for IRB renewal:	**$1,000.00**
Study Modifications *(e.g., protocol amendment, revised informed consent form, updated investigator's brochure, new or revised recruitment materials, new or revised study instruments)*	*Full board review:* **$1,000.00**** *Expedited review:* **$500.00****
Final Report:	**$500.00**
REPORTS OF UNANTICIPATED PROBLEMS/VIOLATIONS:	**No charge**
Reportable Adverse Event submission	**No charge**
Protocol Violation Report submission	**No charge**
SPECIAL LETTER:	**$250.00**

*There is no fee for items that are coming back to the IRB or an expedited reviewer for a follow-up review (e.g., requests for response/follow-up) that have already been billed for the initial review, modification or continuing review. Please review the following "Frequently Asked Questions" for additional details.

Fee is per submission. Multiple revised documents may be packaged into one submission (e.g., protocol amendment + revised informed consent + investigator's brochure). **However, a study modification and continuing review/progress report must be separate submissions.

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For questions, please contact David Gill, PhD, CIP, Manager Human Research Protection Program, at gilld@sutterhealth.org.

Frequently Asked Questions:

How were the charges determined?
The Sutter Health IRB supports and operates on behalf of the entire Sutter Research Enterprise and Sutter research community. Its purpose is to ensure that all human research conducted under the auspices of Sutter Health and its affiliates meets ethical standards, all applicable State and Federal laws, and Sutter Health policies for the protection of research participants. IRB operations are specialized and rigorously regulated. The above fees are charged to help offset the costs of such operations, including expertise-based protocol reviews, administrative support, and technological infrastructure (electronic-based submission system.).

How should investigators cover the cost of the IRB charges?
IRB charges should be included as a line item in any budget where they are an allowed expense.

When will the study be charged?
The IRB will send an invoice following IRB review. The charges apply regardless of whether the project is IRB-approved, a Clinical Trial Agreement (CTA) is signed, the protocol is actually conducted, or other such contingencies. The investigator (or investigator-designee) is expected to forward the invoice to the appropriate individual or sponsor for payment.

What determines whether a study modification is reviewed by the full Board or expedited review?
The determination of review category is made by the IRB Administrator or Chair following an initial assessment after submission. The Sutter Health IRB follows eligibility criteria for expedited review as defined by federal regulations (for more information, see www.hhs.gov/ohrp/policy/expedited98.html); other institutional or regulatory considerations may also apply, depending on the protocol.

Will the IRB waive fees for any studies?
The IRB will waive fees ONLY for the following:

- Residents, fellows, and other students who are conducting studies as a required part of their curriculum or training.
- Government funded or private foundation grant proposals which do not include funds for IRB review.