



University of California
San Francisco

Updated IRB Review Fees

FY22

06/09/2021

Why Must Fees Be Increased At This Time?

- The UCSF IRB's current fee structure for industry-sponsored and UCSF-affiliated studies has fallen far behind a fair assessment for the increasing effort and operating costs of IRB reviews.
- The last fee adjustment was in 2013.

Quick Overview on IRB Fees

<https://irb.ucsf.edu/irb-review-fees>

Only Some Studies Are Subject to IRB Review Fees

- Studies funded by private industry
- Studies submitted on behalf of [UCSF-affiliated institutions](#) (*i.e.*, NCIRE, Gladstone Institutes, San Francisco Department of Public Health, Vitalant, Vitalant Research Institute, Institute on Aging, SF Coordinating Center, Zuckerberg San Francisco General Hospital and Trauma Center, and SF Veterans Affairs Medical Center).

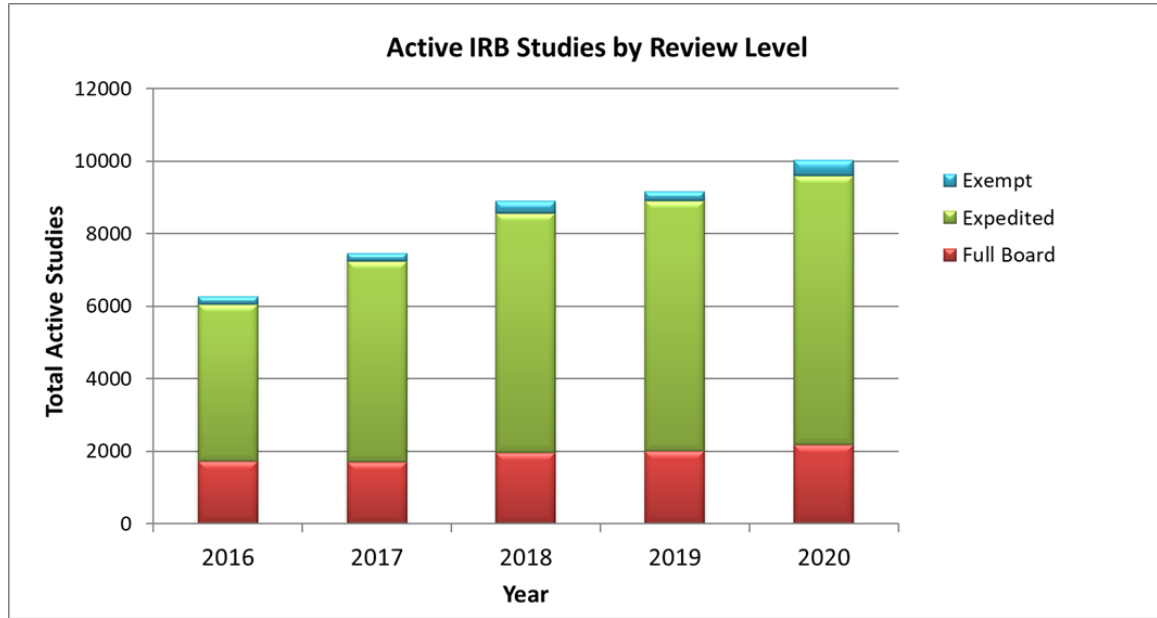
Costs Have Increased

Personnel

- Lean Process Improvement project in 2015 and a reorganization not long after allowed HRPP to operate with a steady number of employees, despite increases in workload.
- Due to merit increases and salary equity initiatives, the cost of salary and benefits increased 45% since 2013.

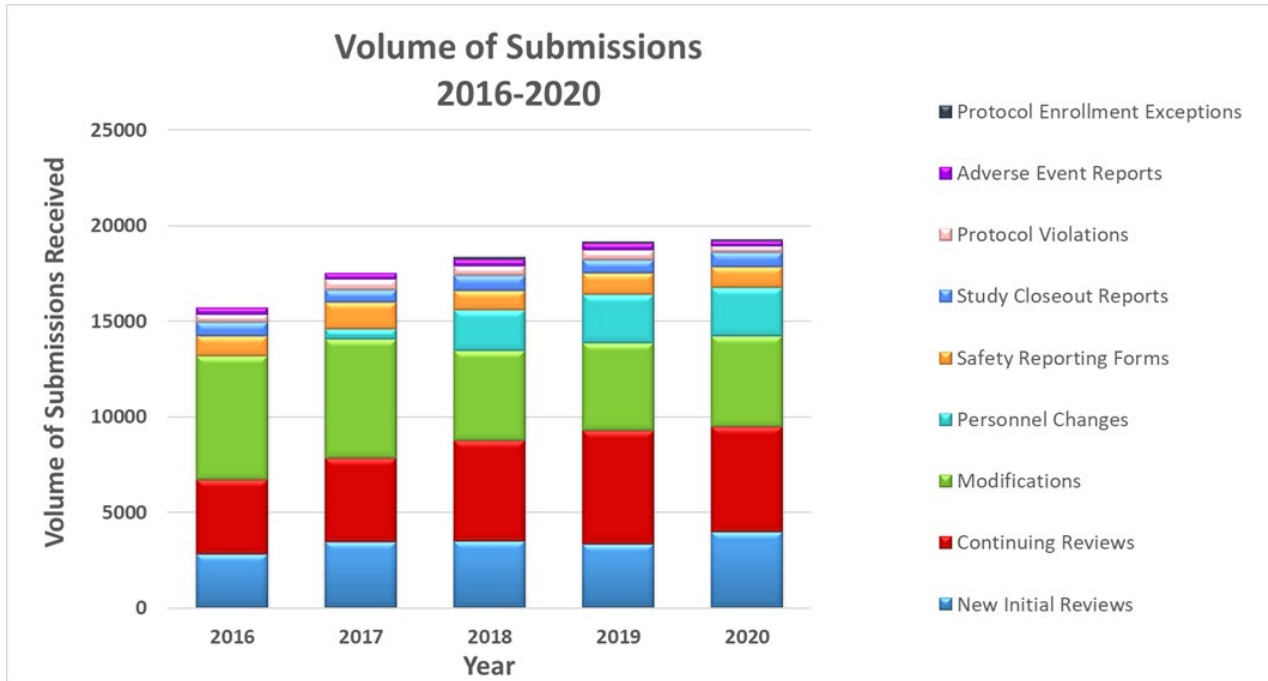
Growth in UCSF Active Studies Over Time

(Does not include ~400 BCH - Oakland studies transferred during 2021)



Change in Volume of Studies Submitted

Includes Post-Review Submission Activities



Other Costs

- IRB System: iRIS maintenance fees increase at the rate of 3% per annum; enhancements and updates are additional costs.

	FY 17-18	FY 18-19	FY 19-20	FY 20-21
Hosting	\$ 57,000.00	\$ 57,000.00	\$ 57,000.00	\$ 57,000.00
Maintenance (3% annual)	\$ 48,925.00	\$ 50,350.00	\$ 51,870.00	\$ 53,426.10
Enhancements, <i>etc.</i>	\$ 3,271.76	\$ 900.00	\$ 45,050.00	\$ 13,000.00

- Pandemic: Unexpected additional costs for laptops, accessories, ergonomics, and other office supplies to support work-from-home.

Limitations on Ability to Generate Revenue from Reviews

- Upward industry trend toward submitting major changes to studies as modifications *versus* new studies.
 - Currently no charge for review of modifications, modest new fee, so incentive to submit major modifications *versus* new study
- Bad Debt from unpaid reviews.

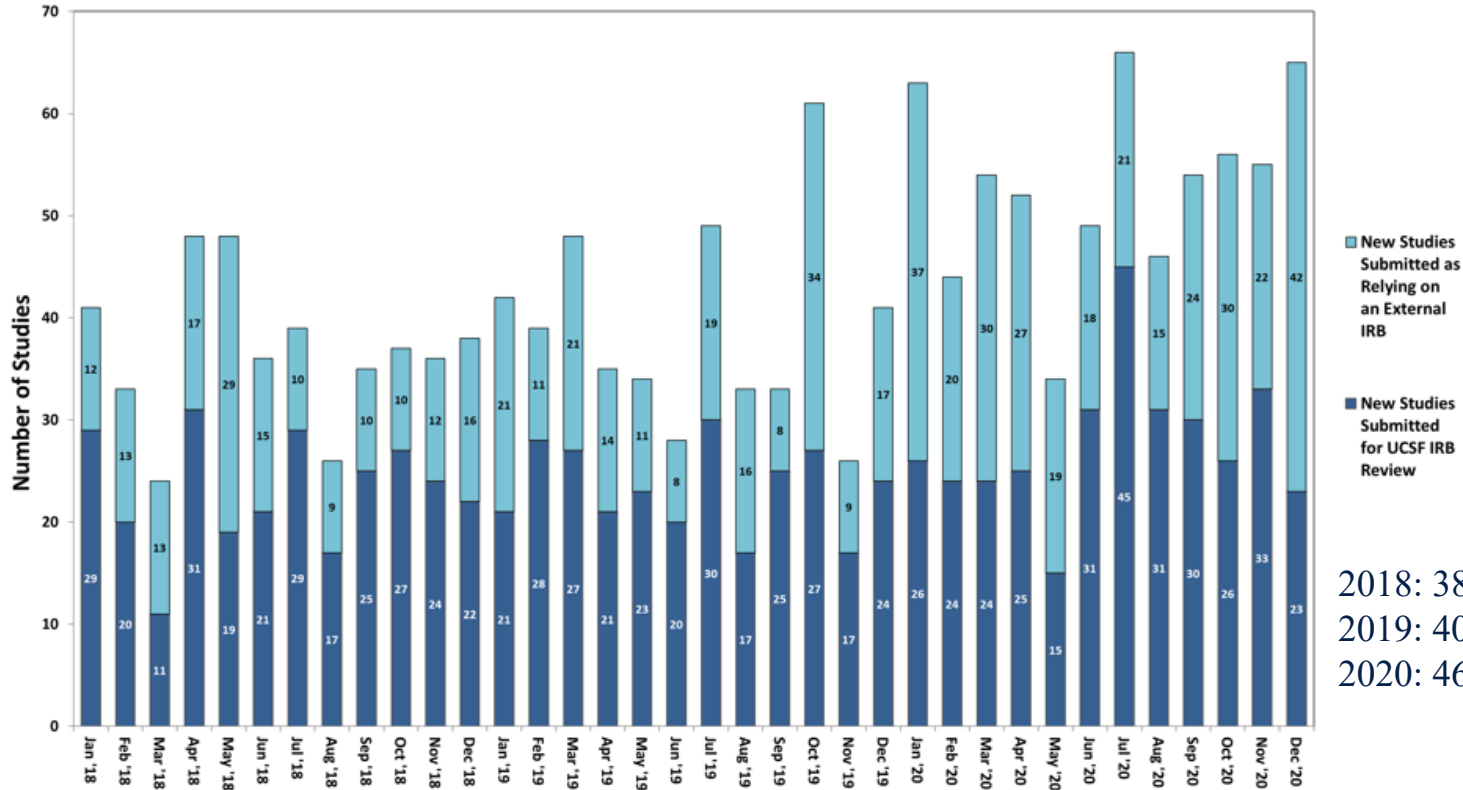
FY 17-18	FY18-19	FY19-20	FY20-21 (Apr 21)
\$ 55,300.00	\$ 16,600.00	\$ 35,000.00	\$ 41,900.00

Lost Revenue Opportunity

- Industry-sponsored studies reviewed by external IRBs reduces ability to generate revenue from in-house review
- HRPP has seen a steady increase in external IRB reliances.

Review of New Full Committee Studies

Volume of Studies for UCSF IRB Review vs. External IRB Reliance



2018: 38% relying (166/441 total)
 2019: 40% relying (189/469 total)
 2020: 46% relying (211/462 total)

Rates Across Peer Institutions

	UCSF Current	UCSF New Rates FY22	UCLA	UCD	UCSD	John Hopkins	Duke Health	Yale
<u>Internal Industry-Sponsored Studies</u>	Effective 2013	Effective 2021	Effective 2012		Effective 2016	Effective 2018	Effective 2016	Effective 2019
Initial Full Committee Review	\$ 2,700.00	\$ 3,630.00	\$ 2,500.00	\$ 3,400.00	\$ 3,510.00	\$ 2,500.00	\$ 2,500.00	\$ 3,500.00
Renewal Full Committee Review	\$ 1,200.00	\$ 2,030.00	No charge	\$ 1,600.00	\$ 1,300.00	\$ 1,250.00	\$ 1,000.00	\$ 1,500.00
Initial Expedited Review	\$ 700.00	\$ 1,210.00	\$ 2,500.00	\$ 3,400.00	\$ 3,510.00	\$ 2,000.00	\$ 2,500.00	\$ 3,500.00
Renewal Expedited Review	\$ 700.00	\$ 1,210.00	No charge	\$ 1,600.00	\$ 1,300.00	\$ 1,000.00	\$ 1,000.00	\$ 1,500.00
Modifications (incl. Personnel Changes, Exception Requests)	\$ -	\$ 230.00	\$ -	\$ -	\$ -	\$ 700-\$800	\$ 750.00	\$ 0 - \$500
Exempt Certification	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 1,000.00	\$ -	\$ -
External IRB Reliance	\$ 700.00	\$ 1,210.00	\$ -	\$800 - \$2,139	\$ 1,300.00	\$ 1,800.00	\$ -	\$ 1,800 (\$1200 annual)
Study Closure	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 250.00
Other fees	\$ -	\$ -	\$ -	\$ -	\$ -	\$500-2500 (Annual)	\$ -	\$ -

Internal & External New Rates

External rates apply to [UCSF-affiliated institutions](#)

Review Services:	Units:	Internal Rates:	External* Rates:
Full Committee (New studies)	per review	\$3,630.00	\$4570.00
Full Committee (Renewals)	per review	\$2,030.00	\$2550.00
Expedited (New and Renewal)	per review	\$1,210.00	\$1530.00
Modification	per review	\$230.00	\$290.00

* Includes 26% Facilities and Administration Rate