

## IRB Review Fees and Yale HRPP Local-Institutional Oversight Fee<sup>1</sup> Schedule<sup>2</sup>

Review Type	INDUSTRY-SPONSORED/INDUSTRY-AUTHORED THIS DOES NOT INCLUDE STUDIES WHERE THE COMMERCIAL ENTITY DID NOT AUTHOR THE PROTOCOL		FEDERALLY FUNDED OR GOVERNMENT AND STATE FUNDED (DOMESTIC AND INTERNATIONAL)		EMERGENCY USE/SINGLE SUBJECT IND		DEPARTMENTALLY FUNDED AND STUDIES WITH NO EXTERNAL SUPPORT		INVESTIGATOR INITIATED/AUTHORED STUDIES WITH EXTERNAL <u>NON-FEDERAL, NON- GOVERNMENTAL, OR NON-STATE SUPPORT</u> (E.G., FOUNDATION, NONGOVERNMENTAL ORGANIZATION, COMMERCIAL, FOR-PROFIT ENTITY, ETC.) <sup>3</sup>	
	Reviewing IRB		Reviewing IRB		Reviewing IRB		Reviewing IRB		Reviewing IRB	
	Yale	External	Yale	External	Yale	External	Yale	External	Yale	External
Initial Review <sup>4</sup>	\$ 3500	IRB of Record fee	\$ 0	IRB of Record fee	\$ 0	IRB of Record fee	\$ 0	IRB of Record fee	\$0 unless included in agreement/grant	IRB of Record fee
Exemption or NOT Human Subjects Research Determination	\$0	IRB of Record fee	\$ 0	IRB of Record fee	\$ 0	IRB of Record fee	\$ 0	IRB of Record fee	\$0	IRB of Record fee
Continuing Review	\$ 1500	IRB of Record fee	\$ 0	IRB of Record fee	\$ 0	IRB of Record fee	\$ 0	IRB of Record fee	\$0 unless included in agreement/grant	IRB of Record fee
Modification: Full Board	\$ 750	IRB of Record fee	\$ 0	IRB of Record fee	\$ 0	IRB of Record fee	\$ 0	IRB of Record fee	\$0 unless included in agreement/grant	IRB of Record fee
Modification: Expedited	\$ 500	IRB of Record fee	\$ 0	IRB of Record fee	\$ 0	IRB of Record fee	\$ 0	IRB of Record fee	\$0 unless included in agreement/grant	IRB of Record fee
Modification: Personnel	\$ 0	IRB of Record fee	\$ 0	IRB of Record fee	\$ 0	IRB of Record fee	\$ 0	IRB of Record fee	\$0	IRB of Record fee
Modification: Change of the PI	\$ 500	IRB of Record fee	\$ 0	IRB of Record fee	\$ 0	IRB of Record fee	\$ 0	IRB of Record fee	\$0 unless included in agreement/grant	IRB of Record fee
Review of Reportable New Information	\$ 0	IRB of Record fee	\$ 0	IRB of Record fee	\$ 0	IRB of Record fee	\$ 0	IRB of Record fee	\$0	IRB of Record fee
Closure	\$ 250	\$ 250 + IRB of Record fee	\$ 0	IRB of Record fee	\$ 0	IRB of Record fee	\$ 0	IRB of Record fee	\$0 unless included in agreement/grant	IRB of Record fee
Yale HRPP Local/Institutional Oversight <sup>5 6</sup>	\$ 0	\$1800 Year 1 + \$1200 annually, starting Year 2	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$0	IRB of Record fee

**Effective date: July 1, 2019: All industry sponsored CTAs that are currently in negotiations or renegotiations with the industry sponsor are subject to the fees at prevailing rates as stated above. In order to request an exception from the fee schedule listed above, please, send your request and the rationale to the HRPP Office at [hrpp@yale.edu](mailto:hrpp@yale.edu).**

<sup>1</sup> IRB fees are non-negotiable and non-refundable and are not contingent upon a fully executed Clinical Trial Agreement (CTA), IRB Approval of the Study, or Site Initiation. Fees will be charged at prevailing rates; they are not locked for the duration of a study.

<sup>2</sup> The schedule applies to Yale HRPP/IRB review of Yale sites only. When serving as the IRB of record for external sites in multi-site research, additional fees may apply. Contact the HRPP Office when budgeting for IRB review of multi-site research.

<sup>3</sup> If the agreement or grant for the Study includes funding for IRB fees, the collected amount will be limited to the actual cost of IRB services not to exceed the specified amount in the agreement or grant.

<sup>4</sup> Includes review of all research associated documents (protocol, consent forms, recruitment materials, IB, etc.)

<sup>5</sup> External IRB means a non-Yale IRB and generally refers to Commercial IRBs but could refer to another external IRB. Industry sponsors are expected to pay IRB fees to such External (non-Yale) IRBs directly.

<sup>6</sup> Includes the HRPP review for compliance with institutional requirements for human subjects research and to provide any necessary applicable local considerations to the External IRB. Charged at the time of initial local review and applied every year after the IRB of Record approval of continuing review. IRB Fees charged by the External IRB are not included in the above and will be subject to the charges imposed by the respective External IRB.