

Office of the Vice Provost for Research

May 9, 2022

To Whom It May Concern:

The Institutional Review Board (IRB) at Penn has an existing process to bill IRB fees for submissions.

Industry-Sponsored Research

As of Fiscal Year 2022-2023, the review fee schedule for industry sponsored research will change. This change was based on a review of multiple peer institution IRB fee schedules. The new fee schedule is in line with the median and average rates across peer institutions.

These IRB fees should be included in contract negotiations, including initial review, whether the study contract is finalized or not. It should be a line item in the budget of the formal contract as an upfront and non-refundable item. The contracts office will help you with this if needed. Most industry sponsors are aware of IRB fees and have included funds for IRB review.

Studies Submitted as of July 1, 2022

All new studies with industry/commercial sponsors submitted to the IRB on or after July 1, 2022, should include the new IRB fee schedule as outlined below:

Review Type	Fee
Initial Review*	
Convened Review	\$3000
Expedited Review	\$2500
Exemption Review	\$1500
Reliance Agreement Initial Administrative Fee	\$1500
Continuing Review	
Convened	\$1750
Expedited	\$1500
Closure	\$250
Amendments	
Convened	\$750
Expedited	\$500

*NOTE: The Initial Review fee is charged even if the study does not commence at Penn, but the IRB review occurred.

All budgets within this timeframe that are negotiated for industry sponsored studies should include the following 4 line items for IRB fees: Initial, Continuing Review(s) (with the number of reviews being based off the proposed duration of the protocol) and modification(s) (which should be captured as invoiced per occurrence), and Closure.

Studies Submitted Prior to July 1, 2022

All studies submitted prior to July 1, 2022 will remain on the old fee schedule, as outlined below.

Review Type	Fee
Initial Review*	\$2400

Continuing Review	\$1000
Modifications requiring convened review or deemed complex	\$500
Administrative Review where Penn is the relying IRB	\$500

*NOTE: The Initial Review fee is charged even if the study does not commence at Penn, but the IRB review occurred.

All budgets within this timeframe that are negotiated for industry sponsored studies should include 3 line items for IRB fees: Initial, Continuing Review(s) (with the number of reviews being based off the proposed duration of the protocol) and modification(s) (which should be captured as invoiced per occurrence).

Single IRB of Record (sIRB) Federally Funded Studies

The IRB may charge fees for serving as the single IRB of Record (sIRB) for federally funded, multi-site studies. The NIH policy states that the IRB of Record should bill for additional administrative fees for external site reviews as direct costs. *This applies to grants submitted to NIH after the effective date of the sIRB requirement (January 2018)*.

The current IRB fee schedule for studies where the Penn IRB is serving as the sIRB is the following:

Review Type	Fee
Initial Review (per relying site)	\$1400
Continuing Review (per relying site with study activity during the last approval period)	\$600
Modifications (fee per affected relying site) excluding any administrative and/or	\$300
minor revisions	

*NOTE: If a relying site is not affected by a modification submitted to the sIRB or if a site has minimal or no activity at the time of request for continuing approval, the fee will not be assessed for that specific submission.

These fees should be included in grant proposals for federally funded, multi-site trials submitted after January 2018. If you have any questions about whether IRB review fees should be included in your proposal budget for multi-site research where you are asking the Penn IRB to serve as the single IRB of record (sIRB), please contact Patrick Stanko.

Single IRB of Record (sIRB) Industry Sponsored Studies:

The sIRB fees described above are in addition to the general fee schedule described under Industry-Sponsored Studies.

Other Important Information

The information needed by the IRB to complete the billing should be included in the HS-ERA application section regarding Industry Sponsored protocols; this section will require you to include an internal financial contact (business administrator) and fund number or budget code. This information should be included at the initial submission, whether the contract is pending or not. The application should also be updated when the contract is complete, that is, changed from pending to finalized.

As of January 4, 2016, the IRB started invoicing and journaling these fees from your departmental research accounts. The billing for IRB fees should be part of your routine invoicing to your funding

sponsor. In addition, the IRB will begin requesting follow-up from either the department Business Administrator or Study personnel if the IRB fees remain unpaid.

As of May 6, 2021, if the IRB billing office is unable to secure a budget code from the department for the charges within two months from the date of billing, they will automatically charge the department's 01XX01 Fund. It will then be the responsibility of the department to reallocate the charges to the correct sponsor project fund.

If you have any questions regarding the content of this memo or how to move forward with budget negotiations related to IRB fees, please feel free to contact Edward Fong, IRB Billing & Financial Business Administrator at <u>edfong@upenn.edu</u> or 215-573-0791.

If you require documentation of the current IRB fee schedule and policies, please visit the IRB website: <u>http://www.upenn.edu/IRB/mission-institutional-review-board-irb/irb-fees.</u>

Thank you for your ongoing commitment to human research at the University of Pennsylvania.

Sincerely,

Jam Abell

Dawn A. Bonnell, PhD Vice Provost for Research Henry Robinson Towne Professor of Engineering and Applied Science Materials Science and Engineering