



**To:** All Faculty and Staff subscribed to the IRB listserv

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**Subject:** Updates to the Temple University IRB Fee Schedule

**Date:** October 1, 2024

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Dear Colleagues,

The purpose of this notification is to provide an update to the Temple University IRB **current IRB fee schedule**. The primary change is updating from a piecemeal, per-submission fee for industry-funded studies that are ceded to an external IRB. We are now moving to a one-time, upfront fee for these studies.

Fees are **assessed** when the Temple University IRB reviews human subject **research studies funded by industry sponsors** (i.e., pharmaceutical or device manufacturing companies), and "investigator-initiated" **research studies sponsored by for-profit entities**. In addition, industry sponsored/for-profit studies for which the Temple University IRB cedes review to an external IRB, are subject to an administrative review and oversight fee.

The table below lists pricing will go fully into effect on October 01, 2024. All applicable Initial Submissions reviewed after February 01, 2025 will be invoiced according to the new fee schedule. Accordingly, clinical trial agreements (CTAs) and contracts that are initiated after this dated memo should incorporate the new fee schedule. **Already approved research and/or finalized clinical trial agreements (CTAs) can maintain the previous fee schedule.**

## **New IRB fee structure**

### **Industry-funded research ceded to an External IRB**

#### **One-time administration fee - \$2500**

A Temple University one-time, administrative IRB fee applies when your study is ceded to an external IRB. The administrative fee of \$2500 is assessed for each protocol and covers the initial local context review, subsequent personnel changes, and oversight of the project. This administrative fee is in addition to the normal review fee to be paid to the External IRB.

### **Industry-funded research with Temple University as the IRB of record**

	<b>Initial Review</b> (protocol and associated material)	<b>Continuing Review</b>	<b>Amendment</b> (excluding administrative/personnel changes)
<b>Full Board</b>	\$2500	\$1000	\$500
<b>Expedited</b>	\$1500	\$800	\$400
<b>Exempt</b>	\$1000	N/A	N/A

### **Applicability**

Temple University human subject research studies that are fully funded by the following sources are not subject to IRB review fees:

- Federal, State, and Local Government
- Internal Institutional grants
- Non-profit foundations and similar organizations that prohibit such fees
- Department or internal discretionary funds
- Other University funds

Additionally, the following submissions will not be assessed IRB review fees:

- Changes in the study personnel, excluding changing the PI.
- Minor Amendments to an approved clinical research study that is not initiated by the sponsor and is administrative in nature.
- Reportable New Information submissions.

### **Budget and Sponsor Information**

All investigators submitting industry-sponsored research protocols to the IRB should incorporate the appropriate IRB fees into their study budget. Payment of IRB fees is regarded as a contractual responsibility of the sponsor. When a study is ceded to an external IRB, the Temple IRB must conduct a local context and compliance review, as per the reliance agreements. This is to ensure that all institutional and local/state law requirements are met. This includes, but is not limited to, ensuring that institutionally required consent language is correct, appropriate HIPAA Authorization documentation, ancillary reviews are conducted, and training requirements for staff are met.

Additionally, the Temple University Human Research Protections Program (HRPP) is ultimately responsible for the oversight of the human subjects research. As such, reviewing changes of personnel and conducting random or for-cause compliance checks can occur. Therefore, industry-sponsored studies will invoke an administrative review fee even when ceded to an external IRB. The administrative review fee is in addition to IRB review fees that may be charged by the external IRB. This fee for services rendered are due in full from the sponsor/CRO, regardless of contract execution, IRB approval, enrollment, or study status.

Should you have any questions or require additional information, please feel free to contact David Comalli at [David.comalli@temple.edu](mailto:David.comalli@temple.edu). As always, we appreciate your continued commitment to research excellence.

*\*Fees are subject to change; A human subject research study that is not designated as industry sponsored but is later determined by the IRB to be industry-sponsored, will be assessed the appropriate IRB fees.*