



**MEMORANDUM**

**TO:** Faculty engaged in research supported by pharmaceutical or device firms and other for-profit entities

**FROM:** Kimberly K. Summers, PharmD  
Assistant Vice President Research

**RE:** UT Health San Antonio Research Review Fees

Research supported by pharmaceutical or device firms and other for-profit entities conducted by UTHealth San Antonio faculty and staff will be charged at the following rates:

	<b>Milestone</b>	<b>Total</b>
<b>UTHSCSA IRB of Record</b>	Initial Review Fees <sup>a, b</sup>	\$5,000
	Annual Fees <sup>a, b</sup> (Fee includes all amendments/modifications reviewed since last approval)	\$2,000
<b>Outside IRB of Record</b>	Initial Review <sup>a</sup>	\$2,500
	Annual Fees <sup>a</sup> (Fee includes all amendments/modifications reviewed since last approval)	\$1,000
<b>Budget and Coverage Analysis Service Fee</b>	Initial Review <sup>c,1,2</sup>	\$2,000
	Modifications <sup>c,3</sup>	\$500
<b>Complion Document Management Fee</b>	Set-up Fee <sup>d</sup>	\$3,500

Fees will **NOT** apply to applications submitted to the IRB that:

- Do not (a) constitute research or (b) involve human subjects
  - Are solely or primarily federally funded\*
- Involve a non-research use of a Humanitarian Use Device
- Are for emergency use or expanded access of an investigational drug or device
- Are supported by Pharmaceutical Companies in which the UT Health San Antonio investigator holds the intellectual property and **NO** information will be shared with the for-profit company

For research in which the UT Health San Antonio investigator shares the intellectual property with the for-profit company, contact the IRB Director for associated fees.

Studies supported by for-profit entities will be billed/ collected by the UT Health San Antonio Clinical Trials Office (CTO); researchers need to account for the applicable review fees in their proposed budgets.

\*For federally funded studies in which UTHSA IRB will be the single IRB for multi-site project, contact the IRB Director for associated fees.

Footnotes

a	<p><b>Institutional approval</b> includes costs associated with maintaining: (1) an AAHRPP accredited Human Research Protection Program (HRPP) to include a formal process to monitor, evaluate, and continually improve the protection of human research participants; dedicating resources sufficient to do so; exercising oversight of research protection; educating investigators and research staff about their ethical responsibility to protect research participants; and, when appropriate, providing a mechanism to intervene in research and to respond directly to concerns of research participants. The HRPP will also monitor compliance with the terms and conditions of the IRB's approval; (2) Assuring and warranting that all investigators participating in the approved research are and will remain members of the Institution's staff in good standing and are credentialed and privileged to perform the procedures outlined in the studies; (3) Assuring that all UTHSA investigators comply with the UTHSA investigator ethics education requirements and other human research related training/education requirements and policies; (4) Following the IRB approval, conducting additional administrative reviews as determined by the UTHSA Institutional Official and UTHSA policy to include the follow: i. ensuring all other institutional committee reviews and approvals are secured (Radiation Safety Committee, Institutional Biosafety Committee, etc.), ii. ensuring funding, billing plans, and payments to participants are in place and Medicare coverage analysis are completed, if applicable, iii. ensuring the research site is adequate for procedures purposed in the protocol and assessing the potential impact on clinical services, iv. ensuring all HIPAA and data security requirements are being met, v. assessing potential Conflict of Interest (COI) disclosures and development of management plans, if applicable, vi. notification and coordination with affiliated sites for the purposed research; and (5) ensuring a mechanism for appropriate reporting to the IRB of the following events: i. termination, suspension, or modification of any clinical privileges of members of its Staff who are participating in the studies approved by the IRB, ii. unanticipated problems involving risks to subjects or others; or any serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB(s) identified by the institution, iii. any contact by the FDA, HHS, or any other persons or entities regarding any of the research approved by the IRB. UTHSA will also notify the IRB office in the event that the FDA or other governmental agency issues the institution any "Notice of Inspectional Observations", "Warning Letters", or other communications citing improper or inadequate research practices with respect to the research approved by the IRB.</p>
b	<p><b>IRB approval</b> includes all of the functions required under 45 CFR Part 46, 21 CFR Parts 50, 56, and 312 and 812 (where applicable), 45 CFR Parts 46.160 &amp; 164 HIPAA Privacy Rule (where applicable), and the human subjects protection requirements of the institution's OHRP-approved Federalwide Assurance (FWA) for the review and continuing oversight of human subjects research.</p>
c	<p><b>Budget approval</b> includes (1) Budget Service: i. Clinical Trial Coverage Analysis Development, ii. Budget Preparation &amp; Negotiation; (2) Technology Services: i. Clinical Trial Management System (CTMS) setup, including patient calendar creation within the CTMS, ii. EPIC (EMR) Research Account Creation &amp; Maintenance, iii. Review of Subject Account Charges, iv. Participant payment setup and ongoing accounting (if applicable)</p>
1	<p>Budget fee is applicable to Non-Cancer Trials Only (contact the Mays Cancer Center to obtain fees for cancer related trials)</p>
2	<p>An addition fee (\$1,000) is applied to complex budgets (e.g., surgical or inpatient trials, non-MCC supported trials)</p>
3	<p>Budget modification fee of (\$500) is applied to Sponsor driven protocol changes, which result in an amendment or modification to the current study budget. This is to cover the cost associated with updating and modifying items listed under footnote c. If a study has been deemed complex the Budget Modification fee is (\$750)</p>
d	<p><b>Document Management and Remote Monitoring</b> includes the initial study set-up and on-going maintenance of the local document management system (Complion). Access will be granted to the study monitor to allow remote monitoring of study regulatory documents.</p>