# Human Research Protection Program Review Fee Policy

The fee schedule for UT Southwestern Human Research Protection Program Department (HRPPD) review of research supported by industry firms or other for-profit entities submitted to the IRB and where the contract is submitted for institutional review* on or after October 15, 2021 will be as follows:

| | Submission Type | Fees |
|---|---|---|
| UTSW IRB Reviews (IRB Review Fees) | Initial Review | $3,000 |
| | Annual Review | $1,500 |
| | Modifications** | $750 |
| External IRB Reviews (HRPP Administrative Review Fees) | Initial Review | $3,000 |
| | Annual Review | $1,500 |
| | Modifications** | $250 |

For any study where UTSW will serve as the IRB of Record for external sites, a single IRB review fee may be assessed to the grant, the funder, the PI, or the relying site(s). Click here to submit a Request for a sIRB Quote or letter of support for a sIRB grant application. The fees will be as follows:

| | | |
|---|---|---|
| Single IRB (sIRB) Reviews | Initial Review | $1,500 - $3,000± |
| | Annual Review | $1,500 - $3,000± |
| | Modifications* | $0 |

*Modifications to onboard relying sites may be assessed an sIRB initial review fee.

The fees apply to the following:

- Research supported by pharmaceutical or device firms and other for-profit entities.
- Research conducted by non-UTSW personnel conducted in accordance with IAAs/MOUs or Research Affiliation Agreements. The fees charged will be as stated in signed agreements.

The studies below are not considered to be fee eligible:

- Do not: (a) constitute research, or (b) involve human subjects
- Qualify for exemption from IRB review
- Are solely or primarily federally funded where there is only one site≠
- 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 UTSW investigator holds the intellectual property and NO information will be shared with the for-profit company
- Are initiated by UTSW investigators≠

## Justifications for Review Fees

**Justification for the IRB Review Fees**

When the UTSW IRB reviews and approves the research, the IRB will ensure that the below regulatory requirements are met in addition to the institutional requirements covered by the HRPP Administrative Review (covered below):

1. All of the functions required under 45 CFR Part 46; 21 CFR Parts 50, 56, and 312 and 812 (where applicable); and 45 CFR Parts 46.160 & 164 HIPAA Privacy Rule (where applicable)
2. The human subjects protection requirements of the institution's Federalwide Assurance (FWA) for the review and continuing oversight of human subjects research.

**Justification for the HRPP Administrative Review Fees**

Although the UTSW is not conducting an IRB review when an external IRB reviews and approves the study, UTSW is required to ensure a high level of compliance with federal regulations, state laws, and local policies and maintain standards to receive accreditation. As such, the HRPP Administrative Review includes all of the following:

1. Maintaining a 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 external 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;
3. Assuring that all UTSW investigators comply with the UTSW 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 UTSW Institutional Official and UTSW policy to include the follow:
5. Ensuring all other institutional committee reviews and approvals are secured (e.g., Radiation Safety Committee, Institutional Biosafety Committee, etc.),
6. Ensuring all HIPAA and data security requirements are being met,
7. Assessing Conflict of Interest (COI) management plans, if applicable, and
8. Notification and coordination with affiliated sites for the purposed research;
9. Ensuring a mechanism for appropriate reporting to the IRB of the following events:
10. Termination, suspension, or modification of any clinical privileges of members of its Staff who are participating in the studies approved by the IRB,
11. 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, and
12. Any contact by the FDA, HHS, or any other persons or entities regarding any of the research approved by the IRB.

**The revised fee schedule will apply to any contract that is submitted for institutional review in our electronic systems on or after October 15, 2021; receipt of a contract before October 15, 2021 by any study team or Department does not constitute submission for institutional review*

*** The modification fees will be charged for any change or updates submitted for review which are initiated or required by contracting entity, regardless of the changes or updates requested*

*± The UTSW HRPP reserves the right to modify the sIRB fees based upon the number of relying sites, the complexity of the study, and/or the funding source*

*ǂFor any study where UTSW will serve as the IRB of Record for external sites, a single IRB review fee may be assessed to the grant, the funder, the PI, or the relying site(s). Click here to submit a Request for a sIRB Quote or letter of support for a sIRB grant application*

# Billing and Payment Procedure

The HRPPD will invoice the sponsor/responsible party for initial review fees and at the time of continuing review for renewal fees. A journal request will be processed by the HRPP and charged to the study accounts following initial approval and after the continuing review has been submitted. All payments received by the sponsor/responsible party will be deposited to the University clearing account and credited to the study account (if one exists). If a study account has not been established, the fee will be credited directly to the HRPP account.

# Lockbox Addresses for Receipt of Checks

## U.S. Mail

UT Southwestern Clinical Trials
P.O. Box 842265
Dallas, TX 75284-2265

## FedEx or Other Courier

Bank of America
Lockbox Services
Attn: Lockbox #842265
1950 N. Stemmons Fwy
Ste. 5010
Dallas, TX 75207
1-800-376-2703 (For courier airbill)

# Tax ID Number

75-6002868

*Note*: Checks should be made payable to "The University of Texas Southwestern Medical Center" and should reference the Principal Investigator's name, protocol number, and invoice number.