Human Research Protection Program (HRPP) Administrative Review Fee Policy

The fee schedule for HRPP Administrative review of all industry developed clinical research of protocols approved by an external IRB and submitted to the HRPP on or after September 1, 2017, will be as follows:

Protocols approved by an External IRB:

- HRPP initial review of externally reviewed protocols $3,000
- HRPP continuing review of externally reviewed Protocol $1,500

There will be no additional charge for modifications, reportable events, or study closure.

HRPP Administrative Review Fees

UTSW will charge an administrative review fee for industry sponsored clinical trials reviewed by an external IRB. UTSW will routinely rely on an external (non-UTSW) IRB for research studies.

Requests to rely on an external IRB should be requested from the HRPP Director by submitting a Reliance Request.

As stated in all IAA/MOU agreements, when relying on an external IRB, UT Southwestern remains responsible for ensuring compliance with the external IRB determinations and bears full responsibility for all research covered under its OHRP-approved Federalwide Assurance.
The above associated fees cover the following activities to ensure UTSW research remains in compliance with the following requirements:

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. Managing all signed IAAs/MOUs and ensuring compliance with the requirements agreed upon by the external IRB and UTSW.
3. 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.
4. Assuring that all UTSW investigators comply with the UTSW investigator ethics education requirements and other human research related training/education requirements and policies.
5. Following the external IRB approval, conducting additional administrative reviews as determined by the UTSW Institutional Official and UTSW policy to include the follow:
    a. Ensuring all other institutional committee reviews and approvals are secured (Subcommittee for Human Use Radiation, Institutional Biosafety Committee, Protocol Review and Monitoring Committee, Laser Committee, etc.)
    b. Ensuring funding, billing plans, and payments to participants are in place and Medicare coverage analysis are completed, if applicable
    c. Ensuring the research site is adequate for procedures purposed in the protocol and assessing

the potential impact on clinical services

d. Ensuring all HIPAA and data security requirements are being met
e. Assessing potential Conflict of Interest (COI) disclosures and development of management plans by the COI Committee, if applicable
f. Notification and coordination with affiliated sites for the purposed research

6. Ensuring a mechanism for appropriate reporting to the external IRB of the following events:
    a. Termination, suspension, or modification of any clinical privileges of members of its Staff who are participating in the studies authorized by the external IRB.
    b. 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.
    c. Any contact by the FDA, HHS, or any other persons or entities regarding any of the research approved by the external IRB. UTSW will also notify the external 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 external IRB.

Billing and Payment Procedure

The Human Research Protection Program Office (HRPPO) will invoice the sponsor/responsible party for initial review fees and at the time of continuing review for renewal fees. An Interdepartmental Requisition (IDR) 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.