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UT HEALTH SCIENCE CENTER™
SAN ANTONIO

MEMORANDUM

TO: Pharmaceutical Company Sponsors

FROM: Kimberly Summers, PharmD
Director of Research Regulatory Programs

RE: Local Review Fee for Studies Reviewed by External Central IRBs

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Research reviewed by an external IRB in accordance with an approved Institutional Authorization Agreement (IAA)/ Memorandum of Understanding (MOU) will be charged at the following rates:

- Initial review fee $2,500
- Review fee $1,000 for all re-approvals

As stated in all IAA/MOU agreements, when relying on an external IRB, UTHSCSA 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 we are in compliance with these requirements:

a) 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.
b) 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.
c) Assuring that all UTHSCSA investigators comply with the UTHSCSA investigator ethics education requirements and other human research related training/education requirements and policies.
d) Following the external IRB approval, conducting additional administrative reviews as determined by the UTHSCSA Institutional Official and UTHSCSA 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
e) Ensuring a mechanism for appropriate reporting to the external 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 authorized by the external 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 external IRB. UTHSCSA 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.