


MEMORANDUM

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

FROM: Brian Herman, PhD, Vice President for Research 

RE: IRB Fee Revision for Pharmaceutical, Medical Device and other for-profit entities

DATE: July 14, 2009

The costs for support of the Health Science Center's three Institutional Review Boards (IRBs), borne by the Office of the Vice President for Research (VPR), have grown to more than \$900,000 per year. The costs have increased due to our response to the research community's request that we increase the efficiency and quality of the IRB service.

Over the past three years, we have substantially revised our staffing and services to include expansion of IRB staff and pre-review services with PIs. This fall we will revise the IRB meeting schedule to increase the frequency of the board meetings to every two weeks and plan to employ an electronic IRB system in the next year.

An increase in the fee for IRB services from \$2,000 to \$2,500 will be implemented beginning August 1, 2009. The IRB fee applies **only** to trials supported by pharmaceutical or device firms and other for-profit entities. A study is considered industry-sponsored when a commercial entity contributes to the design or conduct of the study; coordinates the study as a multi-center trial; reimburses UTHSCSA or a UTHSCSA Investigator for costs associated with conducting the trial; or will have access to, or publish or present the data gained from conducting the trial.

The new fee will continue to be a one-time charge for the initial review of human research (as is the case presently, i.e. no added fee for amendments or continuing review) that will only apply to industry sponsored studies, and will **NOT** apply to the following categories of IRB applications:

- Applications submitted to the IRB that do not (a) constitute research or (b) involve human subjects
- Human research that qualifies for exemption from IRB review
- Human research that is solely or primarily federally funded
- Applications involving a non-research use of a Humanitarian Use Device
- Applications for emergency use of an investigational drug or device

Industry sponsored studies will be billed/collected as in the past. The new fee will be applied to applications submitted for initial review on or after August 1, 2009.