

HAC Submission Fee

Does The HAC Charge For Submissions?

Effective July 1, 2008, all industry sponsored projects submitted for HAC review will be charged an initial submission fee of \$2,500 and a fee of \$500 for each continuing review. There will be no fees for amendments or other protocol related items at this time. These fees are exempt from indirect cost calculations and apply only to the budget's direct costs.

Fees have not increased since July 1, 2000 and our department conducted intensive benchmarking with other universities regarding these fees. Please note that any studies that are currently in the budget negotiation phase will need to include these fees if they will be submitted to the HAC for review after July 1, 2008. Also, all current HAC approved industry sponsored studies will not be charged the continuing review fee; however, all submitted after July 1, 2008 will be charged. The office of Human Research Protection will bill for these charges related to the study.

Does This Fee Ensure A Speedy Process Or Approval?

No. The review process and timetable for these proposals remains the same as for all HAC proposals. The fee is due regardless of the HAC decision and is used to offset costs associated with the HAC review process. The costs include HAC members' stipends, expenses for the meetings, paper costs, faxing costs, database maintenance costs, costs to store files, education and training costs, etc.

What Form Is Required?

A completed HAC Form 112P, Request for Sponsor/CRO, should be submitted with the HAC submission.

Who Does The Billing For These Fees?

The OHRP Business Manager generates a billing statement that contains the protocol submission date and payment due date from the sponsor which are approximately 30 days apart. Failure to submit payment on or before the payment due date will result in a second billing statement being sent to the industry sponsor. A revenue account has been established and oversight is conducted by the OHRP Business Manager. In the event of non-payment by the sponsor, the PI or the department of the PI may be responsible for the fee.

How Do We Request A Fee Waiver Or A Reduced Fee?

A request for fee waiver or reduced fee may be indicated on the HAC Form 112P and submitted to the OHRP Business Manager. Fees are not applied to the following types of protocols:

- NIH grants or other government sponsored studies
- Investigator-initiated studies without pharmaceutical or device company support
- Industry-sponsored studies with budgets less than \$10,000
- Academic studies, foundation or MCGRI sponsored studies

What Should Be Submitted To Request A Fee Waiver Or A Reduced Fee?

A memorandum and a completed HAC Form 112P, Request for Sponsor/CRO, should be submitted to the OHRP Business Manager prior to protocol submission. The memorandum should contain one or two brief paragraphs explaining the research protocol and why it should be considered for a fee waiver or reduced fee. All studies that do not meet one of the aforementioned categories must pay the set fee of \$ 2,500 or the waiver/reduced fee indicated for the review process.

Note: After one year of unsuccessful collections attempts with the sponsor by the OHRP Business Manager, the PI and/or their department will be responsible for the IRB Submission Fee.