



**POLICY STATEMENT REGARDING FEES
CHARGED FOR IRB REVIEW OF
INDUSTRY-SPONSORED STUDIES**

9/23/2008

Effective March 1, 2003, the Duke University Health System (DUHS) Institutional Review Board (IRB) Office began charging fees for all industry-sponsored study submissions requiring full board review. Current fees are posted on the IRB web site and will be assessed for initial review of an industry-sponsored protocol, for continuing review, and for amendments requiring full board review. Continuing review fees will be assessed annually for the duration of the trial. Currently, there is no charge for IRB review of new protocols or amendments which are appropriate for expedited (non-full board) review.

These fees apply only to trials supported by pharmaceutical or device firms and other for-profit entities. The DUHS IRB considers a study ***industry-sponsored*** when a commercial entity contributes to the design or conduct of the study (as evidenced by a sponsor's protocol, Investigator's brochure, etc.); coordinates the study as a multi-center trial; reimburses DUHS or a DUHS Investigator for costs associated with conducting the trial; or will have access to, or publish or present the data gained from conducting the trial. There will be no charge for Federal, State, foundation, investigator-initiated, university-supported or exempt research. There will be no charge for Single Patient Treatment Use Requests.

All investigators submitting industry-sponsored research protocols to the IRB are required to include a separate line item in the study budget for initial and continuing IRB review. Indirect costs should not be applied to these fees; instead investigators should incorporate and negotiate applicable IRB fees into the research contract as direct costs. Payment will be due thirty (30) days from receipt of the protocol submission by the IRB Office or forty-five (45) days from full execution of your research agreement, whichever occurs later. Fees for continuing review will be charged annually until a Final Report form is submitted to the IRB Office.

Payment of IRB fees is regarded as a contractual responsibility of the sponsor. The fees are assessments of actual costs associated with protocol review by the IRB and are charged for services rendered. Because the IRB Office commits its full resources to each review, the fees are due in full from the sponsor, even if the IRB does not approve the study, subjects are never enrolled, or the study is terminated before objectives are reached.

Exemptions will be considered for extenuating circumstances or for small, scientifically significant studies. A request for fee exemption must be submitted by the principal investigator via e-mail to the Associate Dean, Research Support Services. The request should contain the following information: study summary, study budget, justification for conduct of the study at Duke, justification for waiver of the fee for IRB review. The Associate Dean or designee will reply via return e-mail to the principal investigator and the IRB Office.