

IRB Fees for Industry-Sponsored Research**Effective Date: November 1, 2016**

The Duke University Health System charges for Institutional Review Board (IRB) review of research studies supported by pharmaceutical firms and other for-profit entities. There will be no fees for federal, foundation, or investigator-initiated studies. In addition, there are also no fees for expedited reviews or exempt determinations. 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 protocol budget for initial review, continuing review, and amendments that require convened IRB review. Indirect costs should not be applied to these fees. Fees for continuing review will be continued annually until a Final Report form is received by the IRB office.

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 even if the IRB does not approve the study, subjects are never enrolled, a research contract is never executed, or the study is terminated before objectives are achieved. IRB fees are non-refundable.

Any requests for exception should be submitted by the CRU Medical Director to the Associate Dean for Regulatory Oversight.

IRB Fees for convened board review, Effective November 1, 2016*	
Initial protocol review	\$2500
Continuing review	\$1000
Amendments	\$750

*Fees for protocols received by the IRB before November 1, 2016 remain under the previous fee schedule for the duration of the protocol