A. Purpose
The purpose of this policy is to specify how fees for the Institutional Review Board (IRB) review are calculated and processed by Louisiana State University Health Sciences Center – New Orleans (LSUHSC-NO) Human Research Protection Program (HRPP).

B. Policy
It is the policy of LSUHSC-NO to charge for IRB review of industry-sponsored studies as a mechanism to support the administrative costs of such reviews. Non LSUHSC-NO sites in federally sponsored multicenter clinical research studies for which the LSUHSC-NO IRB has agreed to provide oversight as the Single IRB of record are also charged fees to cover costs that would not otherwise be incurred.

C. Scope
This policy applies to all industry-initiated, industry-funded human subject research AND investigator-initiated, industry-funded human subject research submitted to the LSUHSC-NO HRPP for processing and/or review. It also applies to similar research sponsored by private foundations. Excluded from the fee are human subject research protocols funded by federal or state agencies or non-profit foundations and studies supported intramurally (by department, center, school, LSUHSC Foundation).

These fees also apply to investigators from outside LSUHSC-NO that use the LSUHSC-NO IRB for review of their human subject research studies, including when those studies are multicenter federally sponsored projects where LSUHSC-NO has agreed to serve as the Single IRB of record.

D. Procedure
• Fees will be reviewed by the Office of Research Services at least annually. Any institutionally-approved changes will be published on the LSUHSC-NO IRB website and conveyed to active Principal Investigators, Research Administration of all Schools, and the Office of Sponsored Programs. Every effort will be made not to adjust fees on grants where budgets have been finalized.

• Any applicable fee will be added to the budgets of contracts that are entered directly with for-profit companies, as well as subcontracts issued to LSUHSC-NO from another institution. For purposes of calculation of Facilities & Administrative (F & A) costs, this fee should not be included as part of the F&A cost base. The IRB fee must be identified as a line item in the expenditure budget.

• Fees associated with the performance of Single IRB review activities for non LSUHSC-NO sites will be handled as a direct charge to federal grants and therefore the associated revenue and costs will be excluded from the calculation of F & A costs.

• The Office of Research Services will prepare and submit to Accounting Services a journal entry in the amount of the appropriate initial IRB fee upon receiving e-mailed documentation from Sponsored Projects Administration that a PeopleSoft account has been established for the
study. Concurrently, the Office of Research Services will submit an invoice to the study sponsor in the same amount.

- Through the life of the study, the Office of Research Services will prepare and submit to Accounting Services journal entries in amounts appropriate to reflect the actions of the IRB (i.e., continuing review, modification) and will concurrently submit invoices to the study sponsor in those same amounts.

- Fees are non-refundable and not contingent on approval of the study being reviewed.