"HOSPITAL"	**Issue Date** **Revision Dates**

SUBJECT: POLICY RE: FEE FOR INSTITUTIONAL REVIEW OF CLINICAL STUDIES

"HOSPITAL" invests considerable time and expense in the endeavors of the Institutional Review Board (IRB), which evaluates and approves medical research projects proposed by members of the Medical Staff. Sometimes, these studies are being conducted on behalf of for-profit companies (sponsors) in order to obtain approval from the Food and Drug Administration (FDA) to market drugs or devices. In such cases, it is common for the physicians who conduct the studies to receive compensation from the sponsors for their efforts.

Because the IRB's contribution involves administrative costs, copying costs, legal costs and costs associated with providing meeting space and meals, **"HOSPITAL"** hereby adopts the following Policy for seeking compensation to help defray expenses in appropriate cases:

1. The IRB shall review all research proposals in accordance with its Procedural Manual, and shall make its decisions initially to approve or disapprove such proposals, based on the criteria established therein, without regard to the issue of payment under this Policy.

2. When the IRB receives a request for approval of a research proposal involving the testing of an article on behalf of a for-profit entity and in furtherance of that entity's commercial goals for a product, the IRB Chair shall review the request and shall determine whether the sponsor shall be requested to submit a review fee in the amount of _____ **Dollars ($_____)**, or such other amount that the Chair determines appropriate. All requests shall be made on behalf of **"HOSPITAL"** and the proceeds shall be used for the benefit of the institution, as directed by the Administrator.

3. The IRB shall have the discretion to render approval of the study contingent on payment of compensation as requested, or to withdraw approval and terminate the study if compensation is not made, but in no event shall the payment of compensation influence the IRB to approve, perpetuate or renew a study which does not meet the letter and spirit of the standards and criteria established in the IRB's Procedural Manual for the protection of patients.

Approval		**Approval**	
_____	_____	_____	_____
Institutional Review Board	Date	Medical Executive Committee	Date
Approval		**Approval**	
_____	_____	_____	_____
Board of Directors	Date		Date