

THE UNIVERSITY of TENNESSEE

Graduate School of Medicine

Review of financial information in minimizing risks to subjects	Approved by:	UT GSM IRB
	Approval Date	April 19, 2005
	Effective Date:	June 1, 2005

Rationale:

The IRB's mission to determine that the risks to subjects are minimized includes the responsibility to insure that the financial arrangements of a study do not pose undue risks to subjects. The IRB recognizes that some financial arrangements "may affect the rights and welfare of human subjects." (DHHS, *Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection*, May 2004). As a part of its inquiry the IRB may need to determine that: (1) sufficient funding is available to insure completion of the study, (2) the reimbursement arrangements do not raise conflict of interest issues for the investigator, staff or the institution (3) provision for payments to subjects, if any, is reasonable (4) that an accurate disclosure of any of the foregoing information is made to subjects through the informed consent document or other appropriate mechanism.

Policy:

As a part of its review process, the IRB shall evaluate the relevant financial arrangements for each study in order to determine that the risks to human subjects have been minimized and are reasonable in relation to the benefits of the research. Financial arrangements for each study include (but are not limited to) the following information:

- the structure and amount of remuneration to the investigator, staff and/or institution;
- structure and amount of payment for research-related services and procedures; and
- structure and amount of payment to subjects.

Relevant regulatory provisions:

21 CFR 56.109(a) and 45 CFR

46.109(a): "An IRB shall review and have authority to approve ... all research activities covered by these regulations."