Guidance for Conflicts Disclosure in Informed Consent

*To facilitate appropriate disclosure of potential conflicts of interest in the informed consent document, the following suggested language is provided. It is not required to use these specific provisions. Language should be modified to fit the specific facts and circumstances.*

“This study is paid for by {name of sponsor} which {has no financial interest in its outcome} (or) {owns the drug/device being tested and thus has a potential financial interest in the outcome of the study}. Payments are made to the South Alabama Medical Science Foundation and the funds are used to cover expenses of the study and related academic and research activities of the institution. {The investigators and the South Alabama Medical Science Foundation do not have any financial interest in the outcome of the study} (or) {insert disclosure of potential conflict(s) of interest by investigator(s) and/or institution; using examples as the following:

1. The investigator, Dr. ____________ (full name), owns equity (stock) of the company which is paying for this research.

2. The investigator, Dr. ____________ (full name), personally receives consulting, or other payments from the company which is paying for the study.

3. The investigator, Dr. ____________ (full name), is an inventor of {the drug/compound/device, etc}, for which a patent may be filed by the institution. If the patent is pursued, based on data from this and other research, royalties and other compensation may be received by the institution and the investigator. Thus the South Alabama Medical Science Foundation and the investigator have a potential financial interest in the outcome of this study.

“If you require further information regarding financial arrangements described in this paragraph, you should discuss the matter with the study doctor, phone number, or you may contact the Director, Office of Research Compliance and Assurance at 251-460-6625.”