

L. DISCLOSURE OF FINANCIAL INTERESTS:

If no disclosable interests have been identified print “NONE”. Otherwise begin with the following introduction:

"Sometimes a research investigator {or the Mount Sinai School of Medicine, if applicable} owns a financial interest that could be affected by the results of a research study. The Medical School reviews all research proposals and has policies in place to limit the possibility that financial interests will influence how studies are planned and conducted. This section will inform you if such a financial interest exists in this study that you are being asked to participate in."

Continue with the following statements, as appropriate:

1. For studies where investigators or their Departments are paid on a per patient enrolled basis, the consent form should state that:

"The costs of doing this research are paid based on the number of patients enrolled."

2. For studies paid for in whole or in part by the manufacturer of the drug or device under investigation, the consent form should state that:

"The company sponsoring this study manufactures the drug/device being tested and so has a financial interest that could be affected by the outcome of this study."

3. For studies where an investigator holds a non-significant financial interest in the company or in the drug/device under investigation, the consent form should state that

"One or more investigators have a financial interest that could be affected by the outcome of this study."

4. For studies where an investigator receives financial support from the study sponsor that does not exceed the level of significant financial interest, the consent form should state that:

"One or more investigators receive financial support from the study sponsor that is separate from the sponsor's support for this grant."

5. For studies where an investigator holds a significant financial interest in the company or in the drug/device under investigation, the consent form should state that

"One or more investigators have a significant financial interest that could be affected by the outcome of this study."

(Investigators should then specify the nature of this financial interest, e.g. the investigator holds a patent or has equity in a privately held company.)

5. For studies where an investigator receives financial support from the study sponsor that exceeds the level of significant financial interest, the consent form should state that:

“One or more investigators receives significant financial support from the study sponsor that is separate from the sponsor’s support for this grant.”

(Investigators should then specify the nature of this financial interest, e.g. the investigator receives honoraria, serves on an advisory board, holds a patent or has equity in a privately held company.)

6. For studies where the PI's Department and/or the Mount Sinai School of Medicine has a financial interest in the drug or device under investigation or in a company that could benefit from the study findings, the consent form should state that:

“The Principal Investigator’s Department and/or the Mount Sinai School of Medicine has a financial interest (add specifics) that could benefit from the study findings.”

7. For studies where the PI's Department and/or the Mount Sinai School of Medicine receives significant support from the study sponsor, the consent form should state that:

“The Principal Investigator’s Department and/or the Mount Sinai School of Medicine receive significant financial support from the study sponsor that is separate from the sponsor’s support of this study.” (Add specifics)