

SUMMARY
CONFLICT OF INTEREST POLICY FOR INDIVIDUAL HUMAN
SUBJECTS RESEARCHERS

- (1) In accordance with the Faculty Handbook, all potential conflicts of interest should be declared.
 - a. Standard form will be used to declare all conflicts.
- (2) All declarations will be reviewed and categorized as either *significant* or *non-significant* financial interests.
- (3) Even financial interests that do not meet the threshold for significance should be declared in the informed consent. Either one or both of these statements should be included in the consent.
 - a. *“One or more investigators has a financial interest that could be affected by the outcome of this study.”*
 - b. *“One or more investigators receives financial support from the study sponsor that is separate from the sponsor’s support for this grant.”*
- (4) Financial interests that meet the definition of “significant financial interest” will be subject to the rebuttable presumption.
 - a. Significant financial interest include:
 - i. *Anything in excess of \$10,000 of monetary value during the twelve months before of twelve months after a study to PI or related family members. (Anything=stocks, honoraria, consulting fees, gifts, research support.)*
 - ii. *Equity interest of any kind and in any amount, including stock options in a non-publicly traded company.*
 - iii. *License fees or royalty income.*
- (5) If there is a significant financial interest, the investigator is presumed to have a conflict of interest and may not conduct the research at Mount Sinai without establishing compelling circumstances.
 - a. There are certain types of studies that have many safety checks and balances and therefore, will be exempt from the rebuttable presumption.
 - i. Multi-centered studies, with the coordinating center and data analysis center remote from Mount Sinai, and an independent DSMB.
 - b. Investigators with significant COIs will be asked to complete a standard questionnaire to define compelling circumstances.
- (6) All significant financial conflicts of interest that are not exempt from the rebuttable presumption must be reviewed by the full COI committee for compelling circumstances.
- (7) If the committee finds that there are compelling circumstances, a management plan will be needed. The management plan can include:
 - a. Detailed public disclosure.
 - b. Monitoring of research.
 - c. Disqualification of investigator from participation.
 - d. Divesture of interest.
 - e. Other remedies.