

FINANCIAL CONFLICTS OF INTEREST IN RESEARCH TEST YOUR CONFLICTS OF INTEREST IN RESEARCH I.Q.!

EASY



- **TRUE OR FALSE?** *I have to make a financial disclosure every single time I submit a new research application, even if I submit applications two days in a row.*

TRUE! Every GCO application requires that all covered persons disclose whether or not that have any financial interests relevant to that specific project.

- **TRUE OR FALSE?** *This year, I've done consulting work for Hi-Tech Corporation (my fees totaled \$7,000), and I've also been paid by Hi-Tech to give several lectures through their Speaker's Bureau (@2,000/presentation). Now I'm being asked to participate as a site for a research study sponsored by Hi-Tech. Because I wasn't paid more than \$10,000 for any of these activities, I'm sure I don't have a conflict that would be considered significant.*

FALSE! All of the work that you perform for a particular company within a 12-month period will be considered in the aggregate. In this case, you were paid a total of \$11,000 by Hi-Tech, which exceeds the threshold for significant interests.

- **TRUE OR FALSE?** *When I submit manuscripts for publication, I only need to disclose my financial interests if the journal specifically asks me to do so.*

FALSE! If you have financial interests relevant to the research described in the manuscript, the management plan developed for you will require that you always disclose those interests to the public, including in manuscripts and presentations.

MODERATE



- **TRUE OR FALSE?** Research projects sponsored by foundations are subject to the same conflicts of interest review process as projects sponsored by pharmaceutical companies.

TRUE! Whether the sponsor is a federal or other government agency, a foundation, a not-for-profit group or a commercial entity, the disclosure and review process is the same.

- **TRUE OR FALSE:** The NIH wants to know the details of any conflict that I disclose for a federally sponsored grant.

FALSE! Federal regulations require that Mount Sinai informs the NIH of the existence of a conflict, and that Mount Sinai provides reassurances that the conflict is

being appropriately managed. Only rarely would a situation arise where the NIH would request details of the conflict.

- **PICK ONE:** Which of the following conditions might be imposed in a management plan?
 - a) Disclosure of the interests to the public, e.g., in publications and on consent forms
 - b) Role limitations for the conflicted person
 - c) Restrictions on or relinquishment of financial holdings that create the conflict
 - d) Oversight by an impartial party

Answer: Any or all of these conditions might be included in a management plan! Management plans are developed on a case-by-case basis.

- **TRUE OR FALSE?** *Only financial interests greater than \$10,000 are considered significant.*

FALSE! The threshold for significance differs depending on the type of interest. For example, if you own equity in a publicly traded company, significance is defined as holdings worth more than \$10,000 or representing more than 5% of the shares of the company. But if you have a patent relating to the study, this interest is considered significant regardless of the actual or anticipated value of the patent. It is important to read the policy definitions carefully to understand whether a particular interest that you hold will be considered significant. (Although remember that you must disclose ALL interests relevant to the project, regardless of whether they are significant.)

DIFFICULT



- **TRUE OR FALSE?** *My mother-in-law is a major shareholder in the pharmaceutical company that is sponsoring my research project, but since she doesn't meet the definition of a Covered Person no disclosure is required.*

TRUE, BUT... Relevant financial interests of spouses, partners and dependent children of Covered Persons must always be disclosed. Although parents and in-laws do not fall under this requirement, if the interest is substantial and there is any discomfort or concern that this interest might be perceived as able to affect the study in any way, it is wise to disclose it so that the Committee can help to manage and avoid potential problems.

- **TRUE OR FALSE?** *Financial interests relating to Phase III multi-center clinical trials are not subject to the rebuttal presumption.*

TRUE! For most research involving human subjects, the rebuttable presumption applies whenever there is a significant financial interest. However, the rebuttable presumption does not apply to multi-center centered Phase III clinical trials where Mount Sinai is not the data coordinating center. The risks to subjects involved in these type of treatment trials are generally lower and also better defined than in earlier-stage studies. Also, the ability for an individual investigator to influence

research outcomes is limited. A Management Plan would of course still have to be developed to address the conflict.

- **TRUE OR FALSE?** *Because the financial interests that I have in my research project are minor, my project is unlikely to be subject to a compliance audit.*

FALSE! Audits to confirm compliance with management plans may be done on any kind of research project regardless of the type or level of conflict. Mount Sinai is committed to ensuring that all research is performed free of bias, and random audits help confirm that every kind of project is conducted in accordance with requirements.

GENIUS 

- **True or false?** *About eight months ago I accepted an invitation to attend a conference in Europe as a guest of the Acme Corporation. Now Acme is going to sponsor a research project on which I will be the P.I. I have no other on-going relationship with Acme. I have nothing to disclose.*

FALSE! Unless you provided significant service at the conference, e.g., lectured heavily, that all-expense paid trip to Europe was a gift from the Acme Corporation. Gifts or remuneration received within the 12 months preceding a research project must be disclosed when you submit your research application to the GCO. Further, if the total value of the trip exceeds \$10,000, the interest is considered significant. As an aside, please note that under the new Vendor Policy, accepting gifts of any value is prohibited.

- **True or false?** *I'm the P.I. on three different clinical trials sponsored by First-Rate Corporation, and I also happen to have a patent for a procedure used in the study. I'm one of the only people in the country with the expertise to do these studies, and I'm sure I can provide convincing reasons to participate. . The purposes of the studies are quite varied, so I'm assuming that the Conflict of Interest in Research Committee will look at each separately.*

FALSE! Investigators who have multiple projects with the same company will often have those projects linked for purposes of review by the Committee. The Committee needs to understand all of the issues in order to develop an appropriate management plan. Protecting the subjects and the studies often require that the Committee consider the projects both individually and as a whole.