



Frequently Asked Questions on Financial Conflicts of Interest in Research

I. Key Issues to Understand

- **What is a financial conflict of interest in research?** A conflict of interest can arise in several ways: a) when a “Covered Person” -- an investigator responsible for design, conduct or reporting of research as well as senior key personnel on the project (see policy for complete definition) -- might benefit financially from the outcome of a research study (this is known as an “**individual conflict**”); b) when Icahn School of Medicine might benefit from the outcome of a research study (this is known as an “**institutional conflict**”); or c) when an Institutional Official (a member of the Mount Sinai community with a substantial decision-making role, e.g. Dean, Chair, or Division Chief) might benefit financially from the outcome of the research study (this is another kind of “**institutional conflict**”). Sometimes, one or more of these types of conflicts may be present for the same study.
- **Why is financial conflict of interest in research so important?** As an academic medical center, Mount Sinai stands by the integrity of its research. We cannot allow the prospect of personal or institutional gain to cloud our judgment or influence research results, nor can we risk even the appearance of a conflict. The collection, analysis and reporting of data in research studies must always be objective, scientifically sound and defensible. Breaches of integrity can cause a loss of public confidence in our research programs, and could affect our ability to secure extramural support for research. Sometimes, even the perception of a conflict may put our reputation at risk. In order to protect our research programs and our institution, Mount Sinai has a comprehensive policy governing conflict of interest in research. This policy was developed with careful consideration of guidelines from the Public Health Service and the Association of American Medical Colleges.
- **Do financial interests always create a conflict?** Not always. Some types of interests are of more concern than others because the risks are greater. The key for the Financial Conflicts of Interest in Research Committee is to learn about the financial interests, determine whether those interests create a conflict and if so, develop the best approach to manage the conflict.
- **What is the role of the Financial Conflicts of Interest in Research Committee?** This standing Committee of the Dean reviews disclosure statements submitted by project



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investigators and senior key personnel as part of the GCO application. The Committee: assesses the potential risks posed by outside financial interests; determines whether to allow financially conflicted investigator(s) to participate in the proposed research project; and develops study-specific management plans to manage, reduce or eliminate potential financial conflicts. The Committee also reviews and develops management plans for institutional conflicts of interest. The Conflicts of Interest Office maintains records of all decisions.

- **Are all conflicts treated identically?** No. Although there may be similarities among conflicts and situations, each conflict and project is unique. The Financial Conflicts of Interest in Research Committee review includes consideration of many factors, including the nature and size of the financial interest and the type of research.
- **What types of conflicts are of greatest concern?** Conflicts relating to human subjects research undergo the greatest level of scrutiny because of the need to protect the subjects. Financial interests could influence the way in which a conflicted individual enrolls subjects, obtains consent, or analyzes data; if such performance were biased, it could have implications for the safety of the study subjects as well for the conclusions drawn from the study, e.g., the efficacy of a particular treatment. Mount Sinai takes great care to ensure that such conflicts are eliminated or appropriately managed.

II. Disclosure Process

- **Why do I need to complete a research disclosure form if I already submitted my annual Report on Relationships with Outside Entities on Sinai Central?** The institutional disclosure form captures information about all of your financial interests relevant to your work outside of Mount Sinai. In order to protect your privacy, the Financial Interest in Research Disclosure Form is narrower in scope, and focuses on interests relating to a specific research project; that way, the Financial Conflicts of Interest in Research Committee only sees information relevant to your research project, and does not see information that is unrelated to the project.
- **Will the information I disclose remain confidential?** Your responses will only be seen by members of the Financial Conflicts of Interest in Research Committee and may be reviewed by the Office of the Dean. Although generally Mount Sinai will not release



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specific information unless asked to do so by the funding organization, as of August 23, 2012 we will be required by the Public Health Service to provide them with information about the nature of the conflict, the value of any individual financial interest and the management plan. Also, note that the management plan developed for your conflict may require that you disclose certain aspects of your financial relationships to colleagues, trainees or the public, but not specific dollar amounts.

- **What happens if I acquire new financial interests during the course of the study?** Covered Persons are strongly discouraged from acquiring new financial interests during the course of the study. If you do acquire new financial interests, you must disclose them immediately (by updating your on-line annual form as well your research disclosure form, both on Sinai Central) so that the Financial Conflicts of Interest in Research Committee can evaluate the potential relevance to and impact on the study. Remember that acquiring new interests could affect your ability to participate in the study, and could have other repercussions such as alterations in patient consent forms.
- **What must I report for the new NIH travel disclosure requirement?** If you are currently named on an NIH grant or think you might become involved on an NIH-funded project, you should keep complete records of all of your travel (transportation, food, hotels, etc.) paid for or reimbursed by an outside entity other than another academic institution or the government. Even if the travel is not done in connection to your NIH studies, there are indications that the NIH may still consider some travel as a relevant financial interest. We are waiting for the NIH to provide additional guidance on their requirements regarding the reporting of travel, and as their expectations become clearer, we will in turn give you more information.

III. Review and Management

- **Are the disclosure and review processes the same regardless of who the sponsor of the research is?** Yes, the same issues are considered regardless of sponsorship.
- **What is the timeframe for review of disclosures forms?** Once all Covered Person disclosures required for a project are submitted in Sinai Central, the Financial Conflicts of Interest in Research Committee staff begins the review process. Often, if the financial interest is under \$10,000 and the study does not involve human subjects, the case can



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be reviewed and approved by a working group of the Committee that meets weekly. However, large interests and high risk projects require more scrutiny, increasing the likelihood that the full Committee will need to review the case. Sometimes a conflicted individual will be asked to talk with the Committee Chair or with a Committee work group to clarify issues and help expedite the process. The full Committee typically meets monthly to review cases.

- **If I disclose a financial interest, what is the likelihood that I won't be allowed to participate in the research or that the project will be stopped?** Mount Sinai encourages scientific collaboration with industry as a means of developing new and improved scientific, diagnostic and therapeutic products. The Financial Conflicts of Interest in Research Committee makes every effort to develop appropriate, effective management plans that will allow research to proceed.
- **What is the Rebuttable Presumption in human subjects research?** The Rebuttable Presumption states that Covered Persons with individual financial interests may not conduct research involving human subjects unless the Financial Conflicts of Interest in Research Committee determines that the conflicted individual's participation will not compromise the research. This determination is facilitated through completion by Covered Persons of a Convincing Reasons form for the Committee. The Rebuttable Presumption does not apply to Phase II or Phase III multi-center trials for which there is an independent data monitoring organization and Mount Sinai is not the coordinating site. The Rebuttable Presumption also does not apply to intellectual property that has not yet been commercialized and commercialization is not imminent.
- **What restrictions might be placed on investigators conducting human subjects research?** Unless the Financial Conflicts of Interest in Research Committee accepts convincing reasons:
 - An individual generally cannot serve as principal investigator if he/she has any of the following individual financial interests relating to the research project:
 - Individual interest of any kind greater than \$10,000 with the study sponsor
 - Equity of any amount in a privately-held financially interested company
 - Equity representing 5% or more of the ownership in a publicly-traded financially interested company



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- Intellectual property related to the proposed research where the intellectual property has been commercialized or commercialization is imminent
- Restrictions on Mount Sinai as the Study Site:
 - If a principal investigator has equity interest or intellectual property that is or will soon be commercialized, the research cannot be conducted with Mount Sinai as the sole site and Mount Sinai cannot serve as the data coordinating center for a multisite study
 - If an Institutional Official or Mount Sinai owns intellectual property (most often, when Mount Sinai has licensed a patent to a company or commercialization is imminent) or has equity interest in a privately held company, Mount Sinai cannot be the sole site for conducting the research and Mount Sinai cannot serve as the data coordinating center for the study
- **How does the Financial Conflicts of Interest in Research Committee handle patents?**

Both pending patents and issued patents with relevance to your research project are considered to be financial interests and must be disclosed on your Financial Interest in Research Disclosure Form. However, they are managed differently:

 - Pending patents – Pending patents are not considered to pose conflicts of interest. Even so, the Committee generally recommends that in the spirit of transparency you voluntarily disclose these pending patents in presentations and in publications.
 - Issued patents – Issued patents may be deemed to pose conflicts of interest and may require a management plan, particularly if licensing or other commercialization is imminent.
- **Is all royalty income treated in the same way?** Royalty payments from any source must be disclosed by Covered Persons on their Financial Interest in Research Disclosure Form. How they are classified and managed differs depending on whether the royalties are paid through Mount Sinai:
 - Royalties Through Mount Sinai – Royalties paid by Mount Sinai to Covered Persons are not considered individual financial interests. However, royalties which Mount Sinai receives are considered institutional financial interests and will be managed as such by the Committee.



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- Royalties Outside Mount Sinai – Royalties paid to a Covered Person by any entity other than Mount Sinai are considered individual financial interests. If they have relevance to a particular research project the Committee will manage them as conflicts.
- **How will I know when and how my issues have been resolved?** For human subjects studies, the PPHS/IRB will inform you if a management plan has been developed for you to sign. For studies that do not involve human subjects, you will be notified directly by the Financial Conflicts of Interest in Research Committee staff.
- **Once I agree to the Management Plan, is there anything else I need to do regarding conflict of interest and the research project?** You will need to: a) follow the actions outlined in the management plan; b) promptly report any changes in relevant financial interests by submitting an updated disclosure form; and c) cooperate in any project audit undertaken by the Office of Research Compliance.