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Financial Conflicts of Interest in Research

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Icahn School of Medicine at Mount Sinai, a member of The Mount Sinai Health System (together "Mount Sinai") has an obligation to assure that our research is conducted pursuant to the highest standards of ethical conduct free from bias. At the same time, Mount Sinai encourages scientific collaboration with industry and supports collaborative research to develop new and improved diagnostic and therapeutic products. Mount Sinai appreciates, however, that these activities often introduce relationships with industry and other outside entities which have the potential for affecting the approval, design, conduct, monitoring or reporting of a research study. Situations can occur in which an independent observer might conclude that the potential for individual or institutional profit could influence the outcome of a research study.

Therefore, to safeguard the academic integrity of Mount Sinai and its investigators, the institution has adopted a rigorous financial conflicts of interest policy predicated on full disclosure and appropriate management. In order to assure transparency in the conduct of research, Mount Sinai policy requires disclosure of all financial interests regardless of the dollar amount. The Policy sets out the requirements for: disclosing financial interests; reviewing such disclosures as they relate to specific research; determining whether an actual or perceived conflict of interest exists; and determining what appropriate management, if any, should be implemented. Furthermore, the Policy holds that clinical trials to evaluate the safety and efficacy of a drug, medical device or treatment should be held to the most rigorous review and the most stringent requirements.

This Policy is based on the standards set forth in the federal regulations governing research funded by the Public Health Service (PHS) or the National Science Foundation (NSF) (42 CFR Part 50 Subpart F) and the recommendations promulgated by the Association of American Medical Colleges (AAMC).

▼ Definitions

1. **Mount Sinai:** Encompasses The Mount Sinai Health System, Inc., Icahn School of Medicine, The Mount Sinai Hospital, and any subsidiary, corporation or other entity owned or controlled by any of the foregoing.
2. **Financial Conflict of Interest in Research Committee ("FCOIRC"):** A standing committee of the Dean, as described in Faculty Handbook Chapter III.
3. **Financial Conflict of Interest in Research ("FCOIR"):** A Financial Conflict of Interest in Research arises when a financial interest or other opportunity for personal financial gain could affect or have the appearance of affecting the design, conduct, reporting, or direct administration of research.
4. **Covered Persons:**
Covered Persons fall into two categories:
 1. Investigators: Any Principal Investigator ("PI"), co-PI, subrecipient PI and any other individual who is responsible for the design, conduct or reporting of research. This term also means collaborators, consultants, students, technicians and/or postdoctoral fellows to the extent they are responsible for the design, conduct, or reporting of the research.

2. **Senior/Key Personnel:** The Program Director/Principal Investigator and any other person who the Institution identifies as senior/key personnel in the grant application, progress report and any other report submitted to the PHS by the Institution.
5. **Related Parties:** A Spouse/domestic partner and dependent children of Investigators as defined in section 2-4 of this policy.
6. **Institutional Officials:**
Institutional Officials fall into two categories:
1. All Mount Sinai senior management with responsibility for overseeing research, including: Dean(s); President; Chairs; Institute Directors; and Division Chiefs.
 2. Senior leadership of committees and departments involved in research, including: Institutional Review Board (IRB); Program for the Protection of Human Subjects (PPHS)/Institutional Review Board (IRB); Grants and Contracts Office (GCO); Institutional Animal Care and Use Committee (IACUC); Mount Sinai Innovation Partners (MSIP); Financial Conflicts of Interest in Research Committee (FCOIRC); and other faculty and employees as identified by the FCOIRC.
7. **Disclosure:**
The term disclosure refers to two distinct procedures:
1. Internal reporting of Individual Financial Interests by Covered Persons to the Financial Conflicts of Interest in Research Committee and Icahn School of Medicine's Conflicts of Interest Office
 2. External notification of relevant information about a Covered Person's Individual and/or Institutional Financial Interests where relevant, e.g., to research subjects, research funders, in publications and presentations.
8. **Financially Interested Company:** An entity whose financial interests could reasonably appear to be affected by the conduct or outcome of a research project. The term "entity" means any corporation, limited liability company, partnership, limited partnership, limited liability partnership, joint venture, business trust, or other business organization, and any not-for-profit organization, charity or foundation.
9. **Equity Interest:** Any stock of a corporation, or any options, warrants or rights to acquire stock of a corporation, or any notes, debentures or securities convertible into or exchangeable for any stock of a corporation; any membership interest in a limited liability company; any partnership interest in a partnership, limited partnership or limited liability partnership; and any contractual or other right, whether accrued or contingent, evidencing an ownership interest in an entity or a right to a share of the profits or losses of an entity.
10. **Intellectual Property:** Pending or issued patents, copyrights, or trademarks, and all rights to share in the royalties from or income produced by any of the foregoing under licenses, contracts or otherwise, whether accrued or contingent.
11. **Individual Financial Interest:** Anything of monetary value that a Covered Person receives from or owns in a Financially Interested Company, including but not limited to: director's fees; consulting fees; honoraria; scientific advisory board fees; Equity Interest; and Intellectual Property. Individual Financial Interest also includes "in kind" compensation from a Financially Interested Company. NIH-funded investigators must also disclose as Individual Financial Interests all sponsored or reimbursed travel expenses paid for by any entity other than the government or another academic medical center.

Individual Financial Interest does not include:

- Salaries from Mount Sinai
- Grant support for salaries from Mount Sinai
- Royalties received from Mount Sinai
- Reasonable business meals and travel provided for scientific meetings consistent with Mount Sinai's Policy on Relationships with Outside Entities. Exception: As indicated above, NIH-funded investigators must disclose such expenses if paid by an entity other than the government or an academic medical center
- 401K/403B retirement funds or shares held in mutual funds not controlled by the Covered Person
- Royalties paid to inventors by Mount Sinai

Although royalties paid to inventors by Mount Sinai are not considered Individual Financial Interests, royalties which

Mount Sinai receives from an invention or other intellectual property constitute Institutional Financial Interests and so must be disclosed by the covered person (see section II-12 "Institutional Financial Interest").

The scope of financial interests to be disclosed is broad and must reflect both the covered person's research responsibilities and institutional responsibilities. This information is needed to determine whether a financial interest constitutes a FCOI.

12. Institutional Financial Interest:

a. Ownership by Mount Sinai of or receipt by Mount Sinai through its technology transfer activities of:

- Equity and ownership interests of any amount in a non-publicly traded, for-profit entity
- Equity and ownership interests valued at more than \$100,000 in a publicly traded, for-profit entity, excluding equity managed by Mount Sinai's Investment Committee
- Prior calendar year gross revenue, resulting from technology transfer activities, greater than \$100,000 per entity
- Receipt by Mount Sinai, in the prior calendar year, through its Development Office of charitable donations greater than \$100,000 from a commercial entity or foundation that sponsors research at Mount Sinai

b. Receipt by an Institutional Official of direct payments (e.g., consulting fees, royalties) greater than \$25,000 annually from a commercial entity or foundation that sponsors research at Mount Sinai; or equity and ownership interests of any amount by an Institutional Official in a non-publicly traded, for-profit entity.

13. Human Subjects Research: As defined by the Program for Protection of Human Subjects.

14. Rebuttable Presumption: The presumption that an individual with an Individual Financial Interest may not participate in the research in question unless he/she can refute the presumption by demonstrating facts that, in the opinion of the FCOIRC, constitute convincing reasons. See Section IV. A. of this Policy.

15. Management Plan: Written plan setting forth specific restrictions or conditions approved by the FCOIRC to manage, reduce, or eliminate an individual and/or institutional FCOI.

✓ Who Must Disclose

1. Every Covered Person must submit an online Research Disclosure Form. The only exception to the online reporting requirement is described in Section III-A-5 of this Policy.
2. The responsibility for ensuring that disclosure forms are submitted by all Covered Persons lies with the Principal Investigator.
3. Principal Investigators and Institutional Officials who are aware of relevant Individual Financial Interests of family members who are not Related Parties should report such interests but are not expected to inquire into the detailed personal matters of such family members who are not Related Parties.
4. Covered Persons added to the research team during the grant funding period must disclose their Individual Financial Interests before commencing participation.
Covered Persons who are subrecipients, subgrantees, contractors or collaborators with agreements to perform a component of Mount Sinai's primary grant must disclose any Individual Financial Interest to their home institution and Mount Sinai. The home institution must provide written assurance to Mount Sinai's Sponsored Projects Accounting Office that it has managed any Individual Financial Interests of Covered Persons in accordance with the conflicts of interest in research policy of the home institution.
5. Covered Persons who are submitting projects through an external Institutional Review Board (IRB) are not required to submit an online Research Disclosure Form through Sinai Central. Disclosure of financial interests must be made using research disclosure forms specific to the external IRB.

✓ **What Must Be Disclosed**

1. Individual Financial Interests:

- a. All Covered Persons must disclose every Individual Financial Interest regardless of value
- b. All Covered Persons must disclose Individual Financial Interests of Related Parties
- c. Examples of Individual Financial Interests that must be disclosed include but are not limited to:
 - Consulting Fees
 - Compensation for service on an Advisory Board (including scientific advisory boards)
 - Officer's/Director's Fees
 - Honoraria for Lectures/ Teaching
 - Equity Interest of any kind and in any amount in a non-publicly or publicly traded Financially Interested Company
 - License fees, royalty income or the right to receive such payments pursuant to a license, option or other entitlement that is directly or indirectly related to the proposed research or services
 - Intellectual Property that is related to the proposed research or services
 - Travel (for NIH-funded studies only): Federal rules require that all NIH-funded investigators disclose the occurrence of any reimbursed or sponsored travel including the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration, unless the trip is sponsored by a government entity or an academic medical center.

2. Institutional Financial Interests

Principal Investigators have the responsibility to disclose Institutional Financial Interests.

✓ **When and How Disclosure Must Be Made**

Research cannot commence until all Institutional and Individual Financial Interests have been disclosed, reviewed by the FCOIRC and managed as appropriate. Research Disclosure Forms must be completed as part of every research project submission; using this form, the Covered Person identifies which, if any, of his/her Individual or Institutional Financial Interests may be affected by the conduct or outcome of the research.

Annual disclosure updates must be made by all Covered Persons for the duration of the research. All Mount Sinai principal investigators, co-investigators, and mentors must complete a Report of Relationships with Outside Entities on an annual basis. Covered Persons who acquire Individual Financial Interests relevant to the research during the course of the study must disclose such interests immediately and must comply with any subsequently imposed Management Plan.

No research application will be considered complete until approval/clearance has been given by the FCOIRC, IRB, and Grants and Contracts Office (GCO), as applicable.

✓ **Mount Sinai Obligations to Identify, Review and Manage any FCOI**

Under the direction of the FCOIRC Chairperson ("the Chair"), the FCOIRC, its designated subcommittees and/or staff as appropriate, will review disclosures to determine whether there are Institutional or Individual Financial Interests that are related to the research and pose a conflict.

If it is determined that a FCOI exists, an appropriate Management Plan will be developed to manage, reduce or eliminate the conflict. The elements of the Management Plan may include but are not limited to:

- Disclosure to human subjects, sponsors, and/or the research team involved in conducting the study
- Disclosure in publications and presentations and to the public
- Modification of the research plan
- Change of personnel or responsibilities, or disqualification from all or part of the research
- Monitoring of research by independent reviewers (internal and/or external)
- Reduction or elimination of the financial interest
- Periodic Audits

Non-adherence to this Policy, Management Plans or reporting requirements will be reviewed on a case-by-case basis by the FCOIRC and will be reported to the Department Chair and/or to the Dean as appropriate. Individuals

who violate this Policy will be subject to a corrective action plan that may include disciplinary action as provided for in the Faculty Handbook.

▪ **A. Heightened Review Standards for Human Subjects Research**

Mount Sinai's commitment to protect the safety and welfare of human subjects participating in research projects is reflected in the additional scrutiny imposed by the FCOIRC in its systematic and rigorous review and management of financial interests. If an Investigator has an actual or perceived conflict of interest, he/she will be automatically subject to certain requirements and/or restrictions for the conduct of human subjects research that will depend upon:

- the investigator's role in the study team
- the nature of the science
- the stage of the research
- the nature of the Individual Financial Interest
- how closely the Individual Financial Interest is related to the research
- the degree to which the Individual Financial Interest may be affected by the research

These heightened standards for human subject research apply regardless of whether the research is funded by a public agency, a non-profit entity, a commercial sponsor or a private source, and wherever the research is carried out.

▪ **Limitations on Principal Investigators**

In general, investigators may not serve as the PI of a Human Subjects Research study if any of the following conditions related to the proposed research exist:

- Individual Financial Conflicts of Interests greater than \$10,000 with the study sponsor
- Equity Interest of any size in a privately-held Financially Interested Company
- Equity Interest representing 5% or more of the ownership in a publicly-traded Financially Interested Company
- Intellectual Property related to the proposed research or service

▪ **Rebuttable Presumption**

a. **Definition and Application**

Mount Sinai applies the Rebuttable Presumption for human subjects research. Under the Rebuttable Presumption, an individual with an Individual Financial Interest may not conduct research involving human subjects unless the FCOIRC determines that the conflicted individual's participation will not in any way compromise the research. This presumption is not designed to suggest that every financial interest jeopardizes the welfare of human subjects or the integrity of research. Rather, it ensures that Mount Sinai will carefully review any financial interest that might give rise to an actual or perceived conflict of interest, and allows the FCOIRC to consider the Investigator's Convincing Reasons (see Section A-1-c below) that might justify participation in the research project.

b. **Exemptions from the Rebuttable Presumption**

Exempt from the Rebuttable Presumption are:

- 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
- Intellectual Property that has not yet been commercialized and commercialization is not imminent

c. **Convincing Reasons:**

Investigators with Individual Financial Interests may be asked to complete a Convincing Reasons form, a set of questions designed to help the FCOIRC assess possible participation in the study. The FCOIRC considers the following factors in making its determination:

- the stage and nature of the research and the extent to which the research could be performed at other centers
- the degree of risk to the human subjects involved that is inherent in the research protocol
- the extent to which the investigator and/or the institution is uniquely qualified to perform the study; the magnitude and type of Individual Financial Interest and the degree to which it is related to the research
- the extent to which the Individual Financial Interest could be directly and substantially affected by the research, such as increasing financial gains for the investigator
- the extent to which the FCOI can be minimized by effective oversight and

- the extent to which the FCOI can be minimized by effective oversight and management

If the FCOIRC determines that the Convincing Reasons justify the individual's participation in the research project, the FCOIRC will develop a management plan that describes any restrictions and/or requirements imposed on the individual.

Additional specific restrictions may also be mandated depending upon the nature of the science, the stage of the research, the nature of the Individual Financial Interest, how closely the Individual Financial Interest is related to the research, and the degree to which the Individual Financial Interest may be affected by the research.

B. FCOIRC Approval

Management Plans are developed by the FCOIRC and must be signed by the FCOIRC Chair, the Principal Investigator, Conflicted Investigator(s), and/or PPHS as applicable.

For Human Subjects Research, an IRB may either accept the decisions of the FCOIRC or adopt more stringent requirements. The final decision of the PPHS will be communicated to the Principal Investigator, Conflicted Investigator(s), FCOIRC and GCO.

If the Covered Person disagrees with the recommended Management Plan, he/she may appeal in writing to the FCOIRC. The FCOIRC's decision on appeal shall be binding.

C. Required Education

Mandatory training on Mount Sinai's Financial Conflict of Interest in Research Policy must be completed by all individuals listed below. Following initial training, refresher training will be required at least every four years.

- FCOIRC Members and Staff
- Chairs/Alternates and those with signatory authority for grant approval
- Senior leadership of GCO, OTBD, PPHS, and IACUC
- Investigators involved in research
- Other staff involved in the grant submission process as determined by the FCOIRC/IRB/IACUC

D. PHS/NIH/NSF Funded Research

PHS has specific training, reporting, and monitoring requirements for all federally funded grants. Pursuant to these federal requirements, Mount Sinai must report to the NIH all individual FCOIs in accordance with this institutional policy and provide the federal funding agency with certain prescribed information of any identified FCOI.

Further guidance on the current NIH policy is posted online (<http://grants.nih.gov/grants/policy/coi/>).

For PHS/NIH or NSF grants, Mount Sinai reports to the funding agency the existence of a FCOI and certifies that it has been managed, reduced or eliminated satisfactorily. Mount Sinai also makes the requisite notifications to the NIH of any subrecipient investigator's(s') FCOI.

More specifically, Mount Sinai provides the following information to the PHS Awarding Component:

- Nature of FCOI
 - Value of Individual Financial Interest
 - Description of the Individual Financial Interest and how it relates to PHS-funded research
 - Elements of Management Plan
- **E. Record Retention**
- Records of all disclosures and Management Plans will be maintained by the FCOIRC for a minimum of three years from the date of submission of the final expenditure report or, where applicable, from other dates as further specified in 45 CF 74.53(b).

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