Financial Conflicts of Interest in Research

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.

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