

# Faculty Handbook

## CHAPTER VII: Institutional Policies

### POLICY ON FINANCIAL CONFLICTS OF INTEREST IN RESEARCH

As an academic institution, The Mount Sinai Medical Center ("Mount Sinai") has an obligation to assure that its scientific and clinical research is conducted pursuant to the highest standards of ethical conduct free from any improper external bias. At the same time, Mount Sinai encourages scientific collaboration with industry and supports collaborative research geared towards developing new and improved diagnostic and therapeutic products. Mount Sinai appreciates, however, that these economic relationships with industry have the potential for directly and significantly affecting the approval, design, conduct, monitoring or reporting of a research study. Situations can occur in which an independent observer might reasonably conclude that the potential for individual or institutional profit could influence the outcome of a research study. Even in the absence of an actual conflict of interest, such situations may require actions to minimize the appearance of a conflict.

Therefore, to safeguard the academic integrity of both Mount Sinai and its investigators, the institution has adopted a rigorous conflicts policy predicated on full disclosure and appropriate management. The Policy sets out the requirements for disclosing potential conflicts of interest in research and specifies the procedures for reviewing such disclosures and determining what corrective measures, if any, should be instituted. Furthermore, the policy subjects clinical trials that evaluate the safety and efficacy of a drug, medical device or treatment, and research on technology in which the Investigator/Covered Person and/or the Institution has an ongoing financial interest, to the most rigorous review and stringent conditions.

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 Academic Medical Centers.

#### Policy on Financial Conflicts of Interest in Research

##### A. Definitions

1. **Disclosure:** Reporting by Covered Persons of compensation or other financial relationships with companies having a financial interest in the investigators' research or its results.
2. **Covered Persons:**
  - a. **Investigators:** includes the principal investigator, co-investigator and any other person who is responsible for the design, conduct or reporting of research. This term further includes investigators who are subrecipients of a federal grant or who work at an institution that is a subrecipient of a federal grant. The responsibility for ensuring that disclosure forms are submitted for the entire research team lies with the Principal Investigator.

- b. Principal Investigator's and Team Members' Related Parties: includes spouse/domestic partner and dependent children.
- c. Institutional Officials: All senior management including President, Vice Presidents, Deans, Chairpersons, Division Chiefs, Center Directors, Members of the Board of Trustees, Members of the Institutional Review Board (IRB), Members of the Institutional Animal Care and Use Committee (IACUC), Members of the Financial Conflict in Research Committee (FCOIRC), and other faculty and employees as identified by the Audit and Compliance Committee of the Mount Sinai Medical Center. These individuals shall submit an annual disclosure form to the Chief Compliance Officer specifying all remuneration from and/or equity in entities that sponsor research and shall provide updates as appropriate and otherwise specified herein.

**3. Financial Interest:**

Anything of monetary value from a Financially Interested Company, including but not limited to: director's fees; consulting fees; honoraria; gifts; other emoluments or "in kind" compensation such as travel and entertainment from a financially interested company (including those from a third party if the original source is a financially interested company), for any services not directly related to the reasonable costs of conducting the research; equity interest (e.g., stocks, stock options, convertible notes, other ownership interests); and intellectual property rights (e.g., patents, pending patents, copyrights and royalties from such rights). [See Policy on Business Conflicts of Interest.]

Financial interest does not include salaries from Mount Sinai, shares held in mutual funds, or reasonable business meals and travel provided in the regular course of business, nor does it include 401K/403B retirement funds.

**4. Significant Financial Interest:**

- a. Amounts for covered persons that in aggregate:
  - Exceed \$10,000 during the twelve months preceding submission of the disclosure statement; or
  - Are anticipated to exceed \$10,000, during the twelve months following submission of the disclosure statement
- b. Equity interest of any kind and in any amount, including options or entitlement to the same, in a non-publicly traded Financially Interested company
- c. Aggregated equity interest of any kind, including options or entitlement to the same, in a publicly traded, Financially Interested company that exceeds \$10,000 in value or more than 5% ownership interest.
- d. License fees, royalty income or the right to receive such payments pursuant to a license, option or other entitlement to a patent, pending patent or copyright that is directly related to the proposed research or services.

**5. Institutional Significant Financial Interest:**

Where Mount Sinai receives or owns through its technology transfer activities:

- a. Equity interest of any amount in a non-publicly traded entity that supports or may benefit from the research.
  - b. Equity interest greater than \$100,000 or 5% of value in a publicly traded entity that supports or may benefit from the research.
  - c. License fees, royalty income or the right to receive such payments pursuant to a license, option or other entitlement to a patent, pending patent or copyright that is directly related to the proposed research or services.
  - d. Charitable donations greater than \$100,000 from a non-governmental entity that also sponsors research at the Institution.
  - e. Educational grants or donations to a program or department (e.g. funding a fellow or event) greater than \$10,000 in a twelve month period from a non-governmental entity that also sponsors research in that Department or Program.
6. **Financially Interested Company:** Financially Interested company means an entity whose financial interests would reasonably appear to be affected by the conduct or outcome of the research. This term also includes any entity acting as the agent of a financially interested company.
  7. **Mount Sinai Medical Center ("Mount Sinai"):** includes The Mount Sinai Medical Center, Inc., Mount Sinai School of Medicine of New York University, The Mount Sinai Hospital, and any subsidiary, corporation or other entity owned or controlled by any of the foregoing.
  8. **Financial Conflict of Interest in Research Committee ("FCOIRC"):** A standing committee of the Dean, as described in Faculty Handbook Chapter III.
  9. **Human Subjects Research:** As described in Faculty Handbook Chapter VI, Research Environment.
  10. **Rebuttable Presumption:** For research involving human subjects, an individual or Institution with a Significant Financial Interest relating to that research is presumed to have a conflict and may not conduct such research. The individual and/or Institution may rebut the presumption by presenting convincing reasons and an acceptable Management Plan that persuade the FCOIRC that it is appropriate to conduct the research at Mount Sinai.
  11. **Management Plan:** Actions or conditions intended to mitigate, prevent, or eliminate a conflict of interest. Management plans must be approved by the FCOIRC.

#### B. Who Must Disclose

All Covered Persons as defined above in Sections A(2)(a, b, c) must disclose their Financial Interests. The Principal Investigator and all Research Team Members must disclose their Financial Interests, including those of their Related Parties. Principal Investigators and Institutional Officials who are aware of relevant Financial Interests of other family members should report such interest but are not expected to inquire into the detailed personal matters of others. As noted in the definition section, "Investigators" include investigators performing programmatic activity pursuant to a subaward agreement. If the grant involves subawards, then the subrecipient institution must complete an MSSM subaward agreement that includes a discrete COI section directing the subrecipient to certify that the institution has a conflict of interest policy consistent with the federal requirements in 42 CFR Part 50 Subpart F. The Institution must further identify each investigator with a conflict of interest and specify whether the

conflict of interest has been eliminated, reduced or managed. Finally, the subrecipient must provide MSSM with any relevant management plans on an annual basis. MSSM will make the requisite notifications to the NIH of the subrecipient investigator(s)' conflict of interest. If the subrecipient does not have a compliant Conflict of Interest policy then the investigators must comply with the MSSM policy, complete the necessary disclosure questionnaire and comply with the FCOIRC's management plan for any identified conflict.

This obligation applies to all subrecipients, subgrantees, contractors or collaborators carrying out a component of MSSM's programmatic activity. It does not apply to vendors or consultants providing routine goods or services, such as data processing, routine analytical or testing services.

**C. What Must Be Disclosed**

All Financial Interests must be disclosed by each Covered Person. This requirement takes precedence over the provisions for consultative arrangements described in Policy on Consultative Relationships.

All Institutional Officials must disclose all Financial Interests or other relationships with any Financially Interested Company in their annual disclosure form and provide updates as appropriate. Chairpersons must also disclose any grants/donations made to the Department from a Financially Interested Company.

**D. When Disclosure Must Be Made**

Disclosure must be made at the time of submission of a research application. Annual disclosure updates will be required for all Covered Persons for the duration of the research. Annual disclosures will be required for all Institutional Officials.

**E. Disclosure Procedure: Certification of Compliance**

**1. When Submitting a Research Application:**

As part of the research application that is submitted to the Grants and Contracts Office, the principal investigator must enclose for each Covered Person a completed confidential disclosure form provided by Mount Sinai, which has been reviewed and approved by the relevant Department Chair(s). Those investigators conducting human subject research and disclosing a Significant Financial Interest must also complete a convincing reasons questionnaire and may also present a proposed Management Plan. The disclosures and the proposed management plans, if any, will be forwarded by the GCO to the Financial Conflict of Interest in Research Committee for review.

The principal investigator shall review the Conflicts of Interest Database to determine whether the Institution or an Institutional Official has a Significant Financial Interest in the sponsor or a Financially Interested Company. If an Institutional Conflict is identified, the principal investigator will include this information on the disclosure form.

In submitting the research application, Covered Person(s), including the Chairpersons, will be certifying that: they have read and understood this Policy; they have made all the required disclosures; and they will comply with any conditions imposed by Mount Sinai to manage, reduce or eliminate actual or potential Financial Conflicts of Interest. For PHS or NSF funded grants, the official signing the grant application for Mount Sinai will be certifying to the governmental agency that: a written and enforced Conflict of Interest Policy is in place; to the best of his/her

knowledge, all required disclosures have been made; and that any actual or potential conflicts will be adequately managed before expenditure of funds from the grant begins.

**2. During the Period of the Research:**

If a change in Financial Interests occurs as a result of acquiring a new Financial Interest or an increase in the value of a previously disclosed Financial Interest, the disclosure statement must be updated promptly. New investigators who join the research during the grant-funding period must disclose their Financial Interests in accordance with this Policy before they begin such work. In addition, updates must be filed annually with the non-competitive renewal of the grant. For PHS- or NSF-funded grants, the existence of any new Conflict of Interest not covered in the original report to the funding agency must be reported by Mount Sinai to the funding agency and assurances given that it has been resolved or will be resolved within sixty days of its identification.

**F. Determination of Potential Institutional Conflicts of Interest**

The FCOIRC shall create a database of the following potential Institutional Financial Conflicts:

1. All technology licensing activities involving Mount Sinai or any of its faculty members.
2. All charitable donations made from Financially Interested Companies to Mount Sinai that exceed \$10,000.
3. Departmental Grants: The Compliance Office shall provide the FCOIRC Chairperson with a list of all donations/grants exceeding \$10,000 from a Financially Interested Company to a department or program.
4. All Institutional Officials' Significant Financial Interests.

**G. Review Procedure; Management of Conflicts**

The FCOIRC will review all disclosure statements indicating Significant Financial Interests, and will retain discretion to review disclosures below this threshold. In its review, the Committee will consider the foreseeable material effect of the research on the Financial Interest, including factors such as the current and potential value of the Financial Interest, the likelihood of significant impact, and the immediacy or time frame of such an impact. If a protocol presents both an institutional conflict and an individual one, the Committee shall review the proposal first, and will make a determination as to whether the institutional conflict can be appropriately managed and the research can proceed at Mount Sinai. The Committee shall review the individual conflict only after resolution of the Institutional conflict.

1. **For Research Involving Human Subjects:** In the event that the Committee determines that a Covered Person, including all members of the research team and their related parties, or the Institution holds a Significant Financial interest, the Committee will presume that a conflict of interest exists and that the individual may not conduct such research at Mount Sinai. This presumption will apply to all research involving human subjects, 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. This presumption will not apply, however, to phase II or phase III multi-center trials, where there is an independent data monitoring organization and Mount Sinai is not the coordinating site.

The Covered Person and/or the Investigator can rebut this presumption by presenting to the Committee convincing reasons why the research should proceed at Mount Sinai and proposing a Management Plan to minimize the Significant Financial Interest and/or to ensure that the Financial Interest does not affect the conduct of the proposed research. The Committee must be persuaded that the financial conflict will not taint the research and may consider the following factors in making their determination:

- the 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 the financial interest and the degree to which it is related to the research;
- the extent to which the financial interest could be directly and substantially affected by the research such as increasing financial gains for the investigator and/or institution.
- the extent to which the financial interest can be minimized by effective oversight and management

2. **For all Research NOT involving Human Subjects:** The disclosure of a Significant Financial Interest by a Covered Person or the Institution will trigger a review by the FCOIRC to determine if there is a real or apparent financial conflict of interest. If the FCOIRC determines that there is a real or apparent financial conflict, it will consider the following issues in assessing whether the research can proceed at Mount Sinai:

- The nature of the research;
- The magnitude of the interest and the degree to which it is related to the research;
- The extent to which the interest could be directly and substantially affected by the research;
- The extent to which the interest is amenable to effective oversight and management;
- The adequacy of the proposed management and oversight plan for the conflict.

If the FCOIRC determines that there is no real or apparent financial conflict of interest, the FCOIRC Chair will concurrently send notifications to the Investigator and the IACUC (if animals are involved).

The FCOIRC may or may not conclude that there is a real or apparent conflict, in which case the research may not proceed until the Committee review has been completed and a management plan has been approved by the FCOIRC and has been agreed to by the Investigator.

#### **H. Possible Management Plans to Neutralize Conflicts**

When a Financial Interest is directly related to the research and may be substantially affected by it, e.g., an equity interest in a start-up company that manufactures the investigational product, the risk is great and the bar must be high. Yet, carrying out the research at MSSM when the Covered Person has Significant Financial Interests may be justified in some circumstances, for

example, when the individual holding such interests is uniquely qualified by virtue of expertise and experience and the research could not otherwise be conducted as safely or effectively without that individual.

If the Committee determines that the conflict can be neutralized by an appropriate and enforceable management plan, the Committee will allow the research to proceed at Mount Sinai, subject to the implementation of the proposed management plan for the conflict.

These management plans may include, but are not limited to the following:

- a. Disclosure - Disclosure is required in every case regardless of the magnitude of the interest, including: (i) public disclosure of the financial interests of the investigator and of Mount Sinai, if applicable, in all relevant publications, presentations (whether or not academic presentations), including presentations at the level of the covered party's primary department or higher, and (ii) disclosure to the appropriate co-investigators, members of the laboratory or research group, and students or trainees, and (iii) disclosure on human subject consent forms;
- b. Restriction on Equity - (i) placement of stock in escrow until a trigger date specified by the Committee, or (ii) requirement that options, warrants, and similar instruments not be exercised without the prior permission of the Committee;
- c. Limiting the Role of the Investigator with a Financial Interest - requiring that the role of the individual with the financial interest be limited in some way, e.g., the investigator may not be allowed to (i) serve as principal investigator, (ii) analyze data, (iii) determine whether potential subjects are eligible for enrollment, (iv) solicit consent, or (v) determine whether an adverse event report is required;
- d. Oversight - appointment of a disinterested individual or group to monitor the research activity. An oversight committee might be charged, at a minimum, with reviewing abstracts and manuscripts before they are submitted for publication to ensure that the research is conducted and reported according to scientific and ethical standards and that conflict of interest management measures are observed. In other cases, an oversight committee might meet quarterly and review protocols, subject accrual, complications, and other issues as appropriate;
- e. Divestiture - allow research to go forward contingent upon the sale or disposal of specified financial interests by a date certain to eliminate or reduce the financial conflict of interest;
- f. Severance of relationships that pose actual or potential conflicts - for example, relinquishing a seat on a board of directors or terminating a consulting arrangement with an outside entity in order to reduce or eliminate the financial or fiduciary conflict of interest.

The final decisions of the Financial Conflict of Interest in Research Committee will be communicated to the Principal Investigator at the same time as a summary is sent to the IRB and/or IACUC for human/animal research and the Department Chair. All final decisions require the majority of the total number of the committee membership. If the Investigator or the Institution objects to the recommendations of the FCOIRC, they may ask for reconsideration of the Committee's decision. The Investigator and/or the Committee members can ask the Dean of Research to participate in a FCOIRC meeting to reconsider the

convincing reasons for the research to be conducted at Mount Sinai and/or the components of the proposed management plan. Only the members of the Committee shall vote on the application for reconsideration, and the Committee's decision shall be binding.

For human subject or animal research, the IRB and or IACUC may either accept the decisions of the FCOIRC or adopt more stringent requirements. The final decision of these respective Committees will be communicated to the Principal Investigator, department chair, Financial Conflict of Interest in Research Committee and GCO.

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

**I. Reporting to PHS/NSF by the Medical Center**

For PHS or NSF grants, before any expenditure of funds may begin, Mount Sinai must report to the funding agency the existence of a conflicting interest and certify that it has been managed, reduced or eliminated satisfactorily. Generally, neither the specific Financial Interests disclosed, nor the conditions imposed need be reported to the agency, but this information must be provided on request from the agency.

**J. Records**

Records of all disclosures and actions taken will be kept by the Financial Conflict of Interest in Research Committee for a minimum of three years from the date of submission of the final expenditure report or, where applicable, from other dates specified in 45 CF 74.53(b) for different situations.

**K. Administration and Enforcement**

The Dean of the School of Medicine will be responsible for the administration and enforcement of this Policy, and will designate an Institutional Financial Conflict of Interest in Research Officer who will receive and review all disclosures with the Financial Conflict of Interest in Research Committee under this Policy. All Covered Persons must comply fully with this Policy and all applicable regulations. Violations will be considered to be academic misconduct and disciplinary action may be taken by the Dean in accordance with the procedures on disciplinary actions set forth in the Faculty Handbook. In the case of research funded by the PHS, if the failure of a Covered Person to comply with this Financial Conflict of Interest Policy has biased the approval, design, and conduct or reporting of the PHS-funded research, Mount Sinai must promptly notify the Public Health Service Awarding Component of the corrective action taken or to be taken. The PHS may take further action or may refer the matter to Mount Sinai with directions for further action. For research funded by the NSF, any unresolved Financial Conflicts of Interest must be reported to NSF by Mount Sinai. Any questions concerning the application or interpretation of this Policy should be directed to the Chair of the FCOIRC.

**L. Applicability; Coordination with Other Policies**

This Policy is not intended to supersede or replace any other regulations or policies of Mount Sinai, including the Policy on Conflicts of Interest in Business and the Policy Concerning Conflicts of Interest in Equity and Technology Transfer. Specifically, with reference to the latter Policy, which in general relates to situations involving equity interests in entities to which Mount Sinai technology has been licensed or transferred, the standards and requirements of such Policy and of this Policy must both be satisfied.

**M. Training**

Mandatory training on MSSM Conflict of Interest Policies must be completed by:

- Members of the Conflict of Interest Committees
- Chairs/Alternates and those with signatory authority for grant approval
- All personnel involved in the design, conduct or reporting of the research
- All staff involved in the grant submission process
- All Institutional Officials as defined herein

Mandatory refreshers must be completed every 24 months by faculty and personnel defined in K.1 above.