



Financial Conflicts of Interest in Research (FCOIR) Policy

Icahn School of Medicine at Mount Sinai, a member of The Mount Sinai Health System (together “Mount Sinai”) has an obligation to ensure that our research is conducted pursuant to the highest standards of ethical conduct free from bias. Mount Sinai encourages scientific collaboration with industry and supports collaborative research to develop new and improved diagnostics, therapeutics, devices, and other products. Nevertheless, Mount Sinai fully appreciates that faculty and institutional relationships with industry (or other outside entities) has the potential to affect the design, conduct, monitoring or reporting of a research study.

Therefore, in order to safeguard the academic integrity of Mount Sinai and its investigators, the institution has adopted a rigorous financial conflicts of interest policy predicated on disclosure and accountability. In order to ensure transparency in the conduct of research, Mount Sinai policy requires faculty disclosure of all personal 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).

A. Definitions

1. **Mount Sinai:** 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. **Office of Industry Engagement and Conflicts of Interest (“COI Office”)** – The office that supports academia-industry collaborations through development and implementation of policies, processes, and oversight plans that safeguard Mount Sinai research, education, and clinical care. The COI Office provides administrative support to both the Financial Conflict of Interest in Research Committee and the Faculty Business Conflicts Committee.
3. **Financial Conflict of Interest in Research Committee (“FCOIRC”):** A faculty committee that provides a forum for review and approval of policies related to faculty engagement with external entities (both domestic and foreign) as well as a forum for the review and approval of financial conflicts of interest in research management plans. The FCOIRC provides guidance on managing the projects of faculty members with complex, external financial relationships as well as projects involving institutional officials and institutional interests. In addition to senior faculty who are voting members, the committee includes ex officio representation from the Office of Industry Engagement and Conflicts of Interest (“COI Office”), Mount Sinai Innovation Partners (MSIP), the Program for the Protection of Human Subjects (PPHS), Legal, and Compliance.

4. **Faculty Business Conflicts Committee (“FBCC”):** A faculty committee that provides a multidisciplinary forum to oversee faculty engagement with external entities (both domestic and foreign) as well as a forum for the review and approval of faculty business conflicts management plans. The FBCC provides guidance on the approach to manage complex business conflicts arising from faculty requests to be a founder, board of director, or hold senior executive leadership positions in external entities.
5. **Financial Conflict of Interest in Research (“FCOIR”):** A Financial Conflict of Interest in Research arises when a financial interest or other opportunity for financial gain could affect or have the appearance of affecting the design, conduct, reporting, or direct administration of research.
6. **Covered Persons:**
 - a. **Investigators:** Any Principal Investigator (“PI”), co-PI, subrecipient PI, co-investigator, and any other individual who is responsible for the design, conduct or reporting of research. This term also encompasses mentors, collaborators, consultants, students, technicians and/or postdoctoral fellows to the extent they are responsible for the design, conduct, or reporting of the research.
 - b. **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.
7. **Related Parties:** A parent, spouse/domestic partner, and dependent children of covered persons as defined above in this policy. Investigators and key personnel are responsible for disclosing the individual financial interests of their related parties.
8. **Institutional Officials:**
 - a. All Mount Sinai senior management with responsibility for overseeing research, including: Dean(s), President, Corporate Officers, System/ Department Chairs, Institute Directors, and Division Chiefs.
 - b. Senior leadership of the Mount Sinai Health System, including but not limited to senior leaders of committees and departments involved in research, including research support offices: Office of Industry Engagement and Conflicts of Interest (COI Office), 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.
9. **Disclosure:** The term disclosure refers to two distinct procedures-
 - a. Internal reporting of Individual Financial Interests (see definition below) by Covered Persons to the Icahn School of Medicine’s Office of Industry Engagement and Conflicts of Interest (“COI Office”) via Mount Sinai’s electronic disclosure management system (eDMS).
 - b. External notification of relevant information about a Covered Person’s Individual and/or Institutional Financial Interests (see definitions below) as needed, for example to research subjects, research funders, and/or in publications and presentations.
10. **Individual Financial Interest:** Any prior, existing and potential future arrangements/ relationships/ activities that a covered person or their related party (parent, spouse/domestic partner and/or dependent children) has with outside entities, both commercial and non-commercial, whether paid or unpaid, including but not limited to:
 - a. Consulting fees
 - b. Honoraria
 - c. Scientific Advisory Board Fees
 - d. Founder’s/Officer’s/Director’s Fees
 - e. Equity Interest of any kind and in any amount in a non-publicly or publicly traded company;
 - f. Intellectual Property, including license fees, royalty income, or the right to receive such payments pursuant to a license, option, or other entitlement.
 - g. Venture or other capital financing

- h. Any outside employment or other appointments

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:

- a. Salaries from Mount Sinai
- b. Grant support for salaries from Mount Sinai (foreign grants excluded)
- c. Royalties received from Mount Sinai
- d. 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
- e. 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 licensing an invention or other intellectual property constitute Institutional Financial Interests and so must be disclosed by the covered person (see Institutional Financial Interest definition below).

The scope of financial interests requiring disclosure is broad and reflects a covered person’s research responsibilities and institutional responsibilities. This information is needed to determine whether a financial interest constitutes a FCOIR.

11. Institutional Financial Interest:

- a. Ownership by Mount Sinai of or receipt by Mount Sinai through its technology transfer activities of:
 - i. Equity and ownership interests of any amount in a non-publicly traded, for-profit entity
 - ii. 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
 - iii. Prior calendar year gross revenue, resulting from technology transfer activities, greater than \$100,000 per entity
 - iv. 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.
- c. Mount Sinai startups and spinouts

12. 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 for-profit and not-for-profit organization, charity or foundation.

13. 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.

14. **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.
15. **Human Subjects Research:** As defined by the [Program for Protection of Human Subjects](#) (PPHS).
16. **Rebuttable Presumption:** The presumption that covered persons with individual financial interests may not participate in the research involving human subjects unless the Financial Conflicts of Interest in Research Committee (FCOIRC) determines that the conflicted individual's participation will not compromise the research.
17. **Research Management Plan:** Written plan setting forth specific restrictions or conditions to manage, reduce, or eliminate an individual and/or institutional FCOIR.
18. **Foreign Collaborations/Entities:** Foreign entities (external to the United States and US territories) include commercial businesses, charities, universities, and/or governments. Relationships include but are not limited to direct payments (honoraria, gifts, awards, prizes, educational stipends, contributions, grants, hospitality, or travel reimbursement) as well as in-kind contributions (office space, equipment, personnel including post-docs/visiting students). For more information, click here to visit the Policy on [Foreign Collaborations](#).

B. Who Must Disclose

1. Annual Disclosure Requirement

All faculty members (full-time, part-time, adjunct, and voluntary faculty involved in education/research) must complete an annual disclosure of outside financial interests (also known as a Disclosure Profile) in the Mount Sinai Electronic Disclosure Management System (eDMS). Please refer to the [COI website](#) for additional information and policies, including annual disclosure requirements.

2. Research Project-Specific Disclosures

- a. Every covered person listed on a research project must have an electronic Disclosure Profile in eDMS and must complete a project-specific disclosure form (Research Trigger Form)
- b. The responsibility for ensuring that a project-specific disclosure form is submitted by every covered person lies with the Principal Investigator.
- c. Investigators and other study personnel added to an ongoing research project must disclose their Individual Financial Interests before commencing participation.
- d. 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 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.
- e. Research study personnel who are submitting projects through an external Institutional Review Board (IRB) are also required to complete required forms in the eDisclosure Management System (eDMS). For detailed guidance on the Request to Rely (R2R) process for external IRBs, click [here](#).

C. What Must Be Disclosed

1. **Individual Financial Interests:** All covered persons must disclose every individual financial interest (as defined in Section A.8) that they or their related party have, regardless of value.

2. Institutional Financial Interests: All investigators on a research project have the responsibility to disclose institutional financial interests (as defined in Section A.9)
3. Foreign Collaborations: Mount Sinai requires disclosure of all financial support and relationships with a foreign entity. Section A.16 defines foreign entities and collaborations. For more information, click here to visit the [Policy on Foreign Collaborations](#).

D. When and How to Disclose

The eDMS Disclosure Profile is required to be completed within 45 days of hire, annually, and updated (within 30 days) if there are changes to a covered person's financial interests. The eDMS Disclosure Profile must be completed electronically via eDisclosure Management System (eDMS).

Additionally, the Disclosure Profile in eDMS must be reviewed and updated, as applicable, at the time of a research project submission. Research cannot commence until all Institutional and Individual Financial Interests have been disclosed, reviewed by the FCOIRC and managed as appropriate.

In order to initiate a research project, a Triggering Event (TE) must be completed in eDMS. Every person listed on the TE will be prompted to update their Disclosure Profile and complete a Research Trigger Form (the Mount Sinai project-specific disclosure form) in eDMS. The Research Trigger Form is used to determine whether any financial interests pose actual or perceived conflicts with a proposed research project. This form is required for every grant and research project/study.

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

E. 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 potential FCOIR.

If it is determined that a FCOIR exists, an appropriate Research Management Plan will be developed to manage, reduce or eliminate the conflict.

The elements of the Research 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
- Oversight Plans, including but not limited to periodic audits by research compliance
- Independent statistician and data analysis plan

F. Review of Human Subjects Research

1. HUMAN SUBJECTS RESEARCH

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 Investigators have an actual or perceived conflict of interest, they 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.

b. 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:

- Personal compensation greater than \$10,000 annually 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 directly related to the proposed research or service

c. Rebuttable Presumption

i. 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 below) that might justify participation in the research project.

ii. Exemptions from the Rebuttable Presumption

Exempt from the Rebuttable Presumption are:

- Phase IIb 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

iii. 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 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.

2. FCOIR Management Plans

FCOIR Management Plans must be signed by the FCOIRC Chair, the Principal Investigator, Conflicted Investigator(s), and/or Chair/Division Directors as applicable.

For Human Subjects Research, an IRB may either accept the FCOIR management plan or adopt more stringent requirements.

If the Covered Persons disagree with the recommended Management Plan, they may appeal in writing to the FCOIRC. The FCOIRC's decision on appeal shall be binding.

3. Reporting Requirements

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.

4. Record Retention

Records of all disclosures and Management Plans will be maintained by the Office of Industry Engagement and Conflicts of Interest 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).

5. Non-Adherence

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 per the Corrective Action Plan for Faculty Non-Adherence to COI Management.

G. Education and Training

In accordance with Mount Sinai's institutional policy, all research study personnel must complete mandatory training requirements in order to participate in research. Mandatory training on Mount Sinai's Financial Conflict

of Interest in Research Policy and the Rigor, Reproducibility, and Ethical Behavior in Biomedical Research must be completed by all investigators and study personnel involved in research.

In addition, Mount Sinai requires individuals listed below to also complete the mandatory training. Following initial training, refresher training will be required at least every four years.

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

PHS has specific training, reporting, and monitoring requirements for all federally funded grants. Further guidance on the current NIH policy is posted online (<http://grants.nih.gov/grants/policy/coi/>)

H. Commercialization of Technology and COI Management

In accordance with Mount Sinai's institutional policy, faculty must disclose all their Intellectual Property as described in the [Mount Sinai Intellectual Property Policy](#). Such disclosures must be made to Mount Sinai Innovation Partners (MSIP), the MSHS technology transfer office, via the [MSIP Portal](#). For more information on MSIP and how to disclose technology, request agreements, or initiate a discussion with a MSIP representative, please [click here](#).

The federal government has established programs to fund innovation and promote commercialization of new technology. Mount Sinai faculty and researchers are encouraged to pursue these funding opportunities. These innovation grants typically involve both individual and institutional COI, and are governed by both regulatory and institutional rules. As such, all submissions for government funded innovation programs must be reviewed by both the COI Office and MSIP prior to submission.

1. SBIR/STTR Grants

Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) grants are commonly used by faculty to advance commercialization of their technology. These grant require the participation of a qualified small business concern (SBC).

SBIR and STTR grants are submitted by the qualified small business concern (SBC), not by the academic partner. ISMMS investigators that are either proposed subaward PIs for SBIR/STTR grants or proposed PIs of STTR grants submitted by a SBC must review the project with MSIP and COI Office before submission. All investigators participating in SBIR/STTR grants must comply with all SBIR/STTR legislative requirements. Before expenditure of any SBIR/STTR funding, the project will be reviewed again by COI Office to assure that all programmatic requirements have been met.

For additional information on SBIR/STTR grants, please visit the following resources:

- [Mount Sinai's COI webpage on SBIR/STTR](#)
- [SBIR.gov](#)
- [NIH webpage for SBIR/STTR](#)

2. Other Funding Sources

ARPAH-H and DARPA are other potential funding sources targeted for innovation and commercialization of high-potential, high impact technologies. Information can be found at:

- [Advanced Research Projects Agency for Health \(ARPA-H\)](#)
- [Defense Advanced Research Projects Agency \(DARPA\)](#)