

Obligations to Identify, Review and Manage any FCOI

Under the direction of the FCOIRC Chair (“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.

✓ 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

2. Rebuttable Presumption

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.

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

3. 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.

✓ **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.

✓ **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

✓ **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/foi/>).

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 sub recipient 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

✓ **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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