

## CONFLICTS OF INTEREST IN RESEARCH

### I. GENERAL

As an academic institution, Mount Sinai Medical Center must avoid all appearances of improper professional behavior by its faculty, members of the voluntary staff, employees and trustees. A conflict of interest in research may arise when an Investigator/Covered Person (as defined below) has a financial interest which could directly and significantly affect 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 private gain could be influencing 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.

This Policy sets out requirements for disclosing potential conflicts of interest in research and the procedures for reviewing such disclosures and determining what corrective measures, if any, should be instituted. This Policy applies to both research funded by the government and other public sector sources (such as foundations) as well as to research funded by private sector sources. For government or public funded research, 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).

This Policy is more stringent in its reporting and oversight requirements for research funded by private sources because, in many instances, research funded by private, for-profit entities may have a more immediate impact on financial interests. Further, clinical trials to evaluate the safety and efficacy of a drug, medical device or treatment, and research on technology in which the Investigator/Covered Person has an ongoing financial interest, are subject to the most rigorous review and stringent conditions.

### II. CERTAIN DEFINITIONS

The following terms are defined as follows for purposes of the Policy:

--**Conflict of Interest:** refers to those situations set forth in Section IV of this Policy.

--**Investigator/Covered Person:** the principal investigator, co-principal investigator or any other person at the Medical Center who is responsible for, or otherwise involved in, the design, conduct or reporting of the research. This

definition also includes members of the Institutional Review Board, who are responsible for reviewing, approving or monitoring such research. Students, Post-Doctoral Fellows, technical assistants, and others whose work is directly supervised or monitored by an investigator, are not included in this definition as a class. However, when such personnel function as "investigators", because they are independently responsible for, or otherwise involved in, the design, conduct or reporting of some aspect of the research, they are included in the definition.

--**Investigator's/Covered Person's Family:** includes spouse, domestic partners, parents and children. In the case of parents and adult children, an investigator/covered person must use reasonable efforts to determine whether a conflict of interest exists.

--**Financial Interest:** anything of monetary value , including but not limited to: salary or other payments for services (e.g., consulting fees, service on an advisory committee, or honoraria); equity interest (e.g., stocks, stock options, convertible notes, or other ownership interests, excluding interests that result from investments in Mutual, Pension or similar funds over which the Investigator/Covered Person has no direct control); or intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:

- (1) salary or other remuneration received from the Medical Center;
- (2) fees or honoraria which do not exceed \$2000 per annum from any one entity;
- (3) de minimis gifts whose aggregate value does not exceed \$250 per annum;
- (4) reasonable business expenses, including travel and meals provided in the regular course of business.

--**Mount Sinai Medical Center or Medical Center:** includes The Mount Sinai Medical Center, Inc., Mount Sinai School of Medicine of the City University of New York, The Mount Sinai Hospital, and any subsidiaries, corporation or other entity owned or controlled by any of the foregoing.

--**Public Sector Funding:** includes funding from governmental entities, including federal, state and county agencies, and charitable 501(c)(3) foundations.

--**Private Sector Funding**: includes funding from all sources other than Public Sector Funding.

### **III. WHEN DISCLOSURE MUST BE MADE**

A principal investigator and co-principal investigator must disclose potential Conflicts of Interest when the investigator first becomes aware of such a conflict but no later than the date that the research proposal is registered in the Grants and Contracts Office. All other persons included within the definition of Investigator/Covered Person must disclose Financial Interests immediately upon discovery of the potential Conflict of Interest. In the case of IRB members who have potential conflicts, the Dean may choose to manage such conflicts by requiring such members to recuse themselves from the relevant decision or by adopting some other appropriate method that would eliminate the potential conflict.

### **IV. WHAT MUST BE DISCLOSED**

#### **A. Public Sector Funded Research:**

With respect to a research project funded by the Public Sector, an Investigator/Covered Person must disclose any Financial Interests and those of his/her Family:

- (1) that could reasonably appear to be affected by the research; or
- (2) in entities whose financial interests could reasonably appear to be affected by the research; or
- (3) that could create real or perceived bias in the design, conduct, reporting, approval, or oversight of the research.

For research funded by the Public Sector, a Financial Interest is not considered to be significant, and need not be disclosed, if: when aggregated for the Investigator/Cover Person and the Investigator's/Covered Person's Family, it meets both of the following tests: (a) does not exceed \$10,000 in value (as determined through reference to public prices or other reasonable measures of fair market value), and (b) does not represent more than a five percent ownership interest in any single entity. Salary, royalties or other payments that, when aggregated for the Investigator/Covered Person and the Investigator's/Covered Person's Family over the next twelve months, are not expected to exceed \$10,000, are also not considered to be significant, and need not be disclosed.

## **B. Research Funded from the Private Sector**

With respect to a research project funded with Private Sector sources, an Investigator/Covered Person must disclose any Financial Interests of the Investigator/Covered Person and those of his or her Family:

(1) in entities or any of their related entities that provide any funding or support for the research; or

(2) that could reasonably appear to be affected by the research; or

(3) in entities whose financial interests could reasonably appear to be affected by the research; or

(4) that could create real or perceived bias in the design, conduct, approval or reporting or oversight of the research.

## **V. WHO MUST DISCLOSE**

Each Investigator/Covered Person must disclose his or her Financial Interests, as provided above, including those of his/her Family.

Investigators/Covered Persons at other institutions or entities who are collaborators or subcontractors on a research grant, must also disclose their Financial Interests when the application is submitted. Such Investigators/Covered Persons must make the disclosure to the Mount Sinai Medical Center according to the standards for disclosure set forth in this Policy or alternatively, certify to the Medical Center that they have made appropriate disclosure to their respective institutions and certify that their institution's conflict of interest policy is comparable to this one.

## **VI. DISCLOSURE PROCEDURE; CERTIFICATION OF COMPLIANCE**

### **A. When Submitting a Grant Application**

At the time that the principal investigator or co-principal investigator discovers the potential Conflict but no later than when he or she submits the grant application to the Grants and Contracts Office (GCO) for review and approval, each investigator on the proposed grant must submit a written statement which either: (a) discloses all relevant Financial Interests or (b) certifies that he/she has no Financial Interests. All other persons included within the definition of Investigator/Covered Person who must disclose

Financial Interests must do so immediately upon discovery of the potential Conflict of Interest.

A disclosure should describe: (1) the nature of the Financial Interest (e.g., stock or other equity, fees, honoraria, etc.); (2) the source of the interest (e.g., a private corporation) and (3) the value of the interest. This statement, which may be submitted in a separate, sealed envelope, will be forwarded by the Grants and Contracts Office to the administrative official(s) responsible for reviewing the information.

In submitting this statement, the Investigator(s)/Covered Person(s), will be certifying that: they have read and understand this Policy; they have made all the required disclosures; and they will comply with any conditions imposed by the Medical Center to manage, reduce or eliminate actual or potential Conflicts of Interest.

For PHS or NSF funded grants, the official signing the grant application for the Medical Center 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 resolved before expenditure of funds from the grant begins.

#### B. During the Period of the Grant

All disclosures must be updated promptly by the Investigator(s)/Covered Person(s) when a notice of grant award is received. In addition, updates must also be filed with the Grants and Contracts Office during the grant funding period prior to an anticipated change in reportable Financial Interests, but at least annually, with the annual renewal of the grant. A change in reportable Financial Interests may occur as a result of acquiring a new Financial Interest, divesting of a previous Financial Interest, or because of an increase in the value of a previously non-significant Financial Interest.

New investigators who begin work on a grant during the grant funding period (e.g., Investigators using the Clinical Research Center) must disclose their Financial Interests in accordance with this Policy, at the time that they begin such work.

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 the Medical Center to the funding agency and assurances given that it has been resolved or will be resolved within sixty days of its identification.

## **VII. REVIEW PROCEDURE; MANAGEMENT OF CONFLICTS**

When the Investigator or other person submits his or her written disclosure statement, it will be reviewed by a committee appointed by the Dean to determine whether a Conflict of Interest exists.

In reviewing disclosures of Financial Interests, 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 review of the disclosure(s) determines that a Conflict of Interest exists, the committee will recommend to the Dean conditions to manage, reduce or eliminate the Conflict. These may include, among other conditions: public disclosure of the Financial Interest; monitoring of the research by an independent scientist; modification of the research protocol; disqualification of the investigator from participation in all or a portion of the research affected by the Financial Interest; divestiture of the Financial Interest; or severance of the relationship producing the Conflict. With respect to persons who have a Conflict of Interest who sit on Committees that have responsibility for reviewing, approving or monitoring the research, at a minimum, such persons will be asked to excuse themselves with respect to such research. The committee's recommendations will be communicated to the Investigator/Covered Person at the same time as they are sent to the Dean. Investigators/Covered Persons may appeal the recommendations of the review committee to the Dean. The decision of the Dean will be final.

## **VIII. REPORTING TO PHS/NSF BY THE MEDICAL CENTER**

For PHS or NSF grants, before any expenditure of funds may begin, the Medical Center 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.

## **IX. RECORDS**

Records of all disclosures and actions taken will be kept in the Office of the Dean for at least three years after submission of the grant final report to the

funding agency.

## **X. ADMINISTRATION AND ENFORCEMENT**

The Dean of the School of Medicine will be responsible for the administration and enforcement of this Policy, and will designate institutional officials who will receive and review all disclosures under this Policy.

Implementation of this Policy will be monitored by the Board of Trustees.

All Investigators/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 an Investigator/Covered to comply with this Conflict of Interest Policy has biased the approval, design, conduct or reporting of the PHS-funded research, the Medical Center 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 the Medical Center with directions for further action.

For research funded by the NSF, any unresolved Conflicts of Interest must be reported to NSF by the Medical Center.

If the Department of Health and Human Services determines that a PHS-funded clinical research project was designed, conducted or reported by an Investigator/Covered Person with a Conflict of Interest that was not disclosed or managed as required by this Policy, the Medical Center must require that the Investigator(s)/Covered Person(s) involved disclose the Conflict of Interest in each public presentation of the results of the research.

Any questions concerning the application or interpretation of this Policy should be directed to the Dean of the School of Medicine or his/her designee.

## **XI. APPLICABILITY; COORDINATION WITH OTHER POLICIES**

This Policy is not intended to supersede or replace any other regulations

or policies of the Medical Center, including the general Conflicts of Interest Policy and the Interim 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 Medical Center technology has been licensed or transferred, the standards and requirements of such Policy and of this Policy must both be satisfied.