



<b>Title</b>	<b>Institutional Conflict of Interest</b>		
<b>Number</b>	COMP-C009	<b>Effective Date</b>	September 12, 2019
<b>Classification</b>	Administrative	<b>Supersedes</b>	Institutional Conflict of Interest Policy
<b>Department Contact</b>	Compliance — Conflict of Interest		

**Table of Contents**

<b>Policy Section</b>	<b>Page(s)</b>
1. Introduction	2
2. Applicability	2
3. Identification of Institutional Financial Interests	2
4. Review of Institutional Financial Interests and Identification of Institutional Conflicts of Interest	2-3
5. Institutional Conflict of Interest Management	4
6. Gifts and Endowment	4
7. Roles and Responsibilities	4-5
8. Compliance and Enforcement	5
9. Definitions	5-6
10. Resources and Related Policies	6-7



## 1. Introduction

The mission of Memorial Sloan Kettering Cancer Center (MSK) is to lead in the prevention, diagnosis, treatment, and cure of cancer and associated diseases through programs of excellence in research, education, outreach, and cost-effective patient care. MSK's community is developing novel concepts and treatments for cancer care and prevention, and collaboration with industry to promote the translation and practical application of these scientific discoveries to patients everywhere supports this mission. MSK as an institution maintains relationships and collaborates with industry in research and technology transfer activities in order to encourage the translation of MSK's discoveries to the public. These institutional relationships have the potential to present conflicting interests that may compromise — or appear to compromise — the objectivity and integrity of MSK's decision-making related to research, clinical care, education, business, and purchasing. MSK has adopted this Institutional Conflict of Interest Policy (Policy) to identify and manage actual and perceived institutional conflicts of interest in order to safeguard the integrity of research, the safety and trust of human research participants, and the trust of patients, the research community, and the public in the work performed at or under the auspices of MSK.

## 2. Applicability

This Policy applies to potential conflicts relating to both MSK as an institution and, by virtue of their leadership positions in the institution, to Senior Executive Officers in their roles as Institutional Officials, as defined in this Policy.

Senior Executive Officers meeting the definition of an Institutional Official under this Policy are also subject to the [Conflict of Interest and Commitment Policy](#) (Individual COI Policy) and the [Boards of Managers Conflict of Interest Policy](#) (Board COI Policy). Institutional Officials' financial interests are reviewed by this Policy in the context of potential institutional conflicts of interest, while their financial interests and outside activities and interests are reviewed under the Individual COI Policy in the context of potential individual conflicts, and under the Board COI Policy relative to provisions of applicable laws pertaining to conflicts of interest and related party transactions.

## 3. Identification of Institutional Financial Interests

Institutional Financial Interests (Institutional FIs) held by MSK are made available to the Compliance Conflict of Interest Office (Compliance) through regular reports from relevant MSK departments, including the Office of Technology Development (OTD) and the Office of Development (Development). Financial interests of Institutional Officials are disclosed by Institutional Officials in accordance with the Individual COI Policy; these disclosures are maintained by Compliance in MSK's disclosure system for individual conflict of interest (COI) disclosures, eDisclosure.

## 4. Review of Institutional Financial Interests and Identification of Institutional Conflicts of Interest

**4.1 Reviews of Institutional FIs.** Compliance will perform an initial review of Institutional FIs to determine if there are actual or potential Institutional Conflict of Interest (ICOI) concerns. If so, Compliance will bring such cases to the Conflict of Interest Committee (COIC) for review and disposition. The COIC is responsible for reviewing Institutional FIs to determine whether an Institutional FI presents an ICOI. In making such determinations, the COIC may rely upon the advice of Compliance, the Office of the General Counsel (OGC), or the Institutional Review Board (IRB), or on prior precedents in similar cases considered by the COIC. To the extent that the COIC requires specialized clinical or scientific knowledge to make its determinations, it will seek such input from individuals with appropriate expertise, either at MSK or from outside the institution.

The COIC shall conduct a case-by-case analysis and may take into account any of the following, as applicable, in determining whether an ICOI exists and the extent to which it can be managed:



1. Whether the nature and magnitude of the Institutional FI, and the extent to which the MSK activity or decision is related to the interest, could directly and substantially affect the MSK activity or decision, or the MSK activity or decision could directly and substantially affect the Institutional FI;
2. In the case of research, the correlation between the Institutional FI and the aims of the research;
3. In the case of research, the role of the Institutional Official in the design, conduct, reporting, or oversight of the research that could be related to an Institutional Official FI;
4. In the case of research, the structure and design of the research, including aspects of the design that could serve as potential controls (e.g., multi-site, blinded, external data safety monitoring board (DSMB));
5. In the case of research, whether the risk of bias can be effectively managed (e.g., additional oversight or monitoring; disclosure of the ICOI to researchers, collaborators, and research subjects; and disclosure of the ICOI in presentations and publications);
6. In the case of human subject research, the risk level to the rights and welfare of the subjects;
7. In the case of business or purchasing decisions, the existence of objective processes for decision-making, the role of the Institutional Official in the decision-making process, and/or the availability of other qualified persons to make such decisions.

**4.2 Additional Considerations for Potential ICOIs in Research Involving Human Subjects.** MSK will not conduct interventional human subject research at MSK when MSK has an Institutional FI in the product, technology, or company being evaluated absent compelling circumstances, which will be determined by the COIC. In addition to the factors noted in Section 4.1, the COIC will consider whether the unique patient population at MSK and the specialized expertise of MSK clinicians and researchers, facilities, and/or equipment is such that the safety and welfare of human subjects is best served by the research occurring at MSK despite the conflict. In conducting a compelling circumstances analysis, the COIC will take into consideration the best interests of the patients and other relevant factors. It should be noted that MSK's IRB is represented on the COIC.

If the COIC determines that there are compelling circumstances for allowing the interventional human subject research to proceed in the presence of such an ICOI, those circumstances must be documented in the COIC minutes on the matter and communicated by Compliance to the IRB and to the Principal Investigator for any associated research studies.

**4.3 ICOI Determination.** An ICOI exists if MSK's COIC reasonably determines that an Institutional FI could, or could reasonably be perceived to, directly and significantly affect the design, conduct, reporting, review, or oversight of MSK research or the outcome of an MSK activity or decision. An ICOI may arise in situations such as the following:

1. MSK licenses intellectual property to an outside entity and holds royalty or equity interests in the entity that may be materially affected by ongoing MSK research or other MSK activities.
2. An outside entity with which MSK has an Institutional FI sponsors or otherwise supports research at MSK.
3. MSK has an Institutional FI in an outside entity that has a substantial financial or business relationship with MSK.
4. Substantial gifts are given to MSK from an outside entity with which MSK or an Institutional Official has an Institutional FI and which are made directly in association with the development of the donor's technology.
5. An Institutional FI of an Institutional Official affects or appears to affect the decisions of MSK as an institution.



6. MSK enters into a transaction with an outside entity in which it holds an Institutional FI that compromises or appears to compromise the integrity of MSK's research, patient care, education, or training activities, or its institutional reputation.

If the COIC determines that an ICOI exists, the COIC is responsible for determining how to manage, reduce, or eliminate the conflict. All determinations made by the COIC relative to ICOIs shall be considered final.

## 5. Institutional Conflict of Interest Management

If the COIC determines that an ICOI exists, it must determine whether the ICOI is manageable or must be reduced or eliminated. ICOI reduction or elimination strategies may include temporary or permanent divestiture, relinquishment, or termination of MSK's or an Institutional Official's Institutional FI.

For those interests that the COIC determines can be managed, the COIC will develop an ICOI Management Plan with the assistance of Compliance. In developing the ICOI Management Plan, the COIC shall take into consideration the factors outlined in Section 4 of this Policy in order to specifically and adequately address the conflict and the actual or perceived risk to the integrity of the impacted MSK activity. Requirements included in an ICOI Management Plan may include, as applicable:

1. Recusal of an Institutional Official from any decision-making regarding a related proposed activity, arrangement, or decision, and disclosure to the relevant individuals to implement the recusal;
2. Disclosure of the ICOI in relevant publications, presentations, manuscripts, press releases, educational materials, and/or research consent forms;
3. Oversight by a subcommittee of the COIC to provide independent oversight and monitoring of the impacted activity;
4. Such other measures as may be deemed appropriate by the COIC.

Compliance will work with individuals, research teams, and other impacted individuals to ensure that information as to the existence of an ICOI and an ICOI Management Plan is made available.

## 6. Gifts and Endowment

It is the policy of MSK that it will not solicit or accept gifts that in any way limit the ability of investigators to conduct or report the results of research in accordance with the highest scientific, medical, professional, and ethical standards.

The process of decision-making and information regarding assets held by MSK in its endowment are managed by the MSK Investments Office under the guidance of a Chief Investment Officer that functions independently from those involved with operations and the conduct of research. The holdings and investments of MSK are confidential and do not create potential for an institutional conflict of interest under this Policy.

## 7. Roles and Responsibilities

**A. Compliance.** Compliance is responsible for the administration and oversight of MSK's COI program, including the intake and review of individual, institutional, and research-related disclosures; the management of identified conflicts; and the maintenance of COI-related training and policies. Compliance supports the COIC, subcommittees of the COIC, and Joint Conflict of Interest Committee (JCOIC). Compliance will work with individuals, research teams, and other impacted individuals to ensure that information as to the existence of an



ICOI and an ICOI Management Plan is made available. Compliance is responsible for supporting and providing guidance in all COI-related matters.

**B. Conflict of Interest Committee (COIC).** The COIC is made up of representatives from clinical, research, nursing, administrative, and legal functions. The COIC is authorized by the JCOIC as responsible for reviewing and adjudicating conflicts in accordance with this Policy. The COIC, or its designee(s), is charged with:

- Identifying, managing, and minimizing actual and potential conflicts of interest and commitment;
- Proposing guidelines and recommendations to improve COI policy and procedures and decision-making about relationships with industry;
- Promoting the understanding of MSK's conflict policies within the MSK community.

Subcommittees of the COIC will provide independent oversight of specific MSK activities in accordance with certain Management Plans instituted in accordance with this Policy.

**C. Institutional Officials.** Institutional Officials are responsible for the complete and accurate disclosure of all financial interests and outside activities, and those of their Immediate Family Members (i.e., spouse, domestic or civil union partner, dependent children), as defined and outlined in MSK's [Individual COI Policy](#). Individual disclosures made by Institutional Officials must be reviewed in the institutional context as detailed in this Policy.

**E. Joint Conflict of Interest Committee (JCOIC).** The JCOIC is a full committee of MSK's Board of Managers and is charged with the overall oversight of MSK's COI program. The JCOIC is directly responsible for decision-making and management relative to conflict matters for MSK's Senior Executive Officers, board members, and officers.

## 8. Compliance and Enforcement

Compliance is responsible for ensuring compliance with the terms of this Policy. Compliance will provide reports of ICOI matters to the JCOIC.

MSK employees who fail to comply with this Policy, including failure to disclose or submission of an erroneous, misleading, or incomplete disclosure as required by this Policy, or failure to comply with an Institutional Management Plan, may be subject to disciplinary action, up to and including termination of employment.

The Office of the Ombudsperson is an available resource for MSK's community to share and discuss concerns relative to compliance with this Policy and/or other COI-related policies. The traditional avenues of raising compliance questions or concerns, including to Compliance and to MSK's confidential and anonymous compliance hotline, are also available.

## 9. Definitions

**Institutional Conflict of Interest (ICOI):** An ICOI exists if MSK's COIC reasonably determines that MSK's Institutional Financial Interests, which include the financial interests of an Institutional Official acting within their authority on behalf of MSK, could, or could reasonably be perceived to, directly and significantly affect the design, conduct, reporting, review, or oversight of MSK research or the outcome of an MSK activity or decision.

**Institutional Conflict of Interest Management Plan (ICOI Management Plan):** An ICOI Management Plan is a formal written plan describing the action(s) taken by MSK to manage, reduce, or eliminate an ICOI.



**Institutional Financial Interest (Institutional FI):** Institutional FI means any of the financial interests below held by MSK:

1. **Equity Interests.** This includes stock, stock options, and other ownership interests in publicly traded and non-publicly traded entities, regardless of value, received by MSK through its technology licensing activities.
2. **Intellectual Property Rights and Interests.** This includes:
  - a. The receipt of or contractual right to licensing revenue, milestone payments, and/or royalties from an external commercial entity to which MSK has licensed intellectual property pursuant to a license agreement;
  - b. Other intellectual property rights and interests that are related to patents and copyrights held by MSK, regardless of whether income has been received, where the technology underlying the patent or copyright was developed at MSK and licensed to an external commercial entity.
3. **Significant Gifts.** This includes an institutional gift or donation to MSK at the level of \$1 million or more in a single transaction, and/or gifts or donations to MSK (or multiple gifts in a given year) exceeding \$25,000 per year to benefit the research or laboratory of an identified MSK researcher, laboratory, or department that participates in the interventional human subject research technology of the donor.
4. **Institutional Officials FIs.** Institutional FIs *also* include the following financial interests held by an Institutional Official (or an Immediate Family Member):
  - a. Ownership or equity interests in publicly traded for-profit entities of an amount exceeding \$25,000 in value (*excluded are equity or ownership interests through personal retirement accounts, mutual funds, or other diversified investment vehicles to the extent that the Institutional Official does not control investment decisions*);
  - b. Any ownership or equity interests (including stock, options, warrants, and the like), ownership, or founders' interests in non-publicly traded for-profit entities;
  - c. Any executive officer or fiduciary role or position, such as service on the board of directors, with a for-profit organization;
  - d. Compensation, including royalty payments, consulting, speaking or advisory fees, or other payments from for-profit organizations that, in the aggregate, exceed \$25,000 per year from a single entity.

**Institutional Official:** For the purposes of this Policy, the term "Institutional Official" includes MSK's Senior Executive Officers (the President, Physician-in-Chief, Chief Operating Officer, Chief Financial Officer, and Director of the Sloan Kettering Institute) and their Immediate Family Members (i.e., spouse, domestic or civil union partner, dependent children).

**MSK:** Memorial Sloan Kettering Cancer Center and its affiliates, the Sloan Kettering Institute for Cancer Research and Memorial Hospital for Cancer and Allied Diseases.

**Senior Executive Officers:** The President, Physician-in-Chief, Chief Operating Officer, Chief Financial Officer, and Director of the Sloan Kettering Institute.

## 10. Resources and Related Policies

For guidance relative to this Policy or related policies, please contact the Compliance COI Team at 212-



639-7612 or [ecoi@mskcc.org](mailto:ecoi@mskcc.org). Guidance and training materials are available on OneMSK.

## Related Policies

- A. [Code of Conduct](#)
- B. [Conflict of Interest and Commitment Policy](#)
- C. [Board of Managers Conflict of Interest Policy](#)