



<b>Title</b>	<b>Conflict of Interest and Commitment</b>		
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<b>Classification</b>	Administrative	<b>Supersedes</b>	Policy on Financial Conflict of Interest and Conflict of Commitment
<b>Department Contact</b>	Compliance — Conflict of Interest		

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## 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 participation in outside activities that promote the translation and practical application of these scientific discoveries to patients everywhere supports this mission. MSK recognizes that while MSK employees have an opportunity to improve and advance cancer care and research through outside activities and collaborations with industry, such relationships may give rise to conflicts of interest or commitment with their MSK responsibilities. MSK has adopted this Conflict of Interest and Commitment Policy (Policy) to identify, review, and manage situations that may give rise to conflicts. MSK will permit, disclose, and manage outside interests and relationships in the context of preserving and protecting MSK's commitment to its mission and community.

This Policy holds that a conflict of interest (COI) exists when an individual's personal financial interests could directly and significantly impact their MSK responsibilities, or an individual's personal financial interests could be directly and significantly impacted by their MSK responsibilities, and a conflict of commitment exists when an individual's outside activities interfere with or detract from their MSK responsibilities.

MSK's Compliance COI Office (Compliance), in coordination with MSK's Conflict of Interest Committee (COIC) and under the oversight of MSK's Joint Board Conflict of Interest Committee (JCOIC), is responsible for the administration of this Policy.

## 2. Applicability

This Policy applies to financial interests or relationships and/or outside activities, whether paid or unpaid, that create or reasonably appear to create a conflict of interest or commitment in the context of an individual's MSK Institutional Responsibilities, which include the design, conduct, reporting, review, or oversight of research, clinical care, business or purchasing decisions, and/or mentoring or supervision of trainees and students.

This policy applies to Covered Persons and their Immediate Family Members.

## 3. External Interests, Relationships, and Activities

While employees can have external financial interests and relationships and engage in outside activities related to their MSK responsibilities, those interests and activities should not influence the employee's professional judgement or bias or interfere with their MSK responsibilities in any way.

**3.1 External Financial Interests and Relationships.** External personal financial interests or relationships (Financial Interests) that an MSK employee has with external entities related to their Institutional Responsibilities may introduce or appear to introduce a conflict of interest. Covered Persons must disclose Financial Interests to MSK in the manner detailed in Section 5 of this Policy.

**3.2 Outside Activities or Interests.** Regardless of whether a Financial Interest exists, outside activities and relationships (e.g., consulting, speaking, advising), even if not compensated and/or not providing personal financial benefit, could present conflict concerns. Likewise, outside interests (e.g., intellectual property), even if not generating revenue, could also present conflict concerns. Therefore, Outside Activities and Interests related to a Covered Person's Institutional Responsibilities, even when not compensated or non-monetary, require disclosure to MSK in the manner detailed in Section 5 of this Policy.

**3.3 Review and Approval.** Covered Persons who engage in outside activities, regardless of whether they receive compensation, must ensure that their immediate supervisor is aware of and approves of the activity. Supervisors should consider whether the time requirements or nature of the activity could compromise the Covered Person's



ability to fulfill their Institutional Responsibilities.

Additionally, any independent outside activities with for-profit or foreign entities that involve written agreements for services between the outside entity and the Covered Person must first be submitted for legal review; these agreements should be submitted in the Consulting, Advisory, Speaking Agreements (CASA) module in MSK's eContracts system.

**3.4 Executive Officer Roles.** Covered Persons should not hold executive officer roles (e.g., Chief Executive Officer [CEO], Chief Operating Officer [COO], Chief Scientific Officer [CSO], or Chief Financial Officer [CFO]) in external for-profit companies that do business with MSK or are related to MSK's mission while concurrently holding their MSK position. Subject to review and approval by Compliance and/or the COIC, executive positions that Covered Persons are permitted to hold include but are not limited to:

- Early-stage start-up companies that are formed by that Covered Person in their area of expertise (the COIC may impose limits on the tenure of such executive roles);
- For-profit entities formed by a Covered Person for the sole purpose of providing personal consulting services;
- For-profit entities whose business is completely unrelated to the Covered Person's Institutional Responsibilities or MSK's mission (e.g., legacy family business).

**3.5 Board of Directors Positions.** All requests for a Covered Person to serve on a for-profit board of directors must be reviewed and approved by the COIC in advance. MSK recognizes that service on a board of directors can be beneficial, and there may be circumstances in which such service should be allowed. However, board of directors service by Covered Persons for a for-profit entity must be compatible with the interests of MSK's mission. MSK Senior Executive Officers are prohibited from for-profit board of directors service. If an MSK employee is designated as a board member on the board of directors of an MSK Spin-Off, any compensation to the MSK representative must be redirected to MSK. MSK employees with a title of Senior Vice President or above will not be permitted to serve as an MSK representative on the board of directors of an MSK Spin-Off.

**3.6 Consulting, Speaking, and Advisory Engagements.** Involvement in consulting, speaking, and advisory activities (including scientific advisory boards) related to a Covered Person's Institutional Responsibilities, whether compensated or non-compensated, is permitted providing the activity does not present unmanageable conflict of interest or conflict of commitment concerns or involve any of the prohibited activities detailed in Section 3.7 of this Policy. The nature of the services that a Covered Person may perform on behalf of an external entity as a consultant or adviser are the provision of advice and the exchange of ideas.

The review and approval process detailed in Section 3.3 of this Policy must be met where applicable.

**3.7 Prohibited External Activities.** Certain activities are prohibited by their nature and/or the terms and conditions that accompany such activities; they include the following:

- Participation in speakers' bureaus sponsored by pharmaceutical, biotechnology, medical device, or other for-profit entities is prohibited.
- Participation in speaking or educational activities where content is controlled by pharmaceutical, biotechnology, medical device, or other for-profit entities is prohibited (i.e., outside entities may not require specific content or materials or have any approval rights over content or materials).
- Endorsement of products or commercial ventures is prohibited. Employees approached to represent MSK on any activity that can be construed as an endorsement must gain approval by the Senior Vice President and Chief Communications Officer or their designee, in accordance with MSK's Endorsements Policy.
- Interactions with industry specifically prohibited in MSK's Policy for Interaction with Industry.



## 4. Conflict of Commitment

A conflict of commitment exists when an individual's Financial Interests or Outside Activities and Interests interfere with or detract from their Institutional Responsibilities.

**4.1 Commitment.** MSK employees' primary professional obligations are to MSK, and their primary professional commitments of time and intellectual energies are expected to be devoted to clinical care, research, education, and other activities supporting MSK's mission. While employees can engage in outside activities in the area of their MSK responsibilities, those activities should not impinge on the employee's ability to perform their professional duties and should not interfere with or detract from their Institutional Responsibilities. Conflicts of commitment generally develop when an employee's outside activities impose excessive demands on their time and/or when an employee enters into a fiduciary relationship with an outside entity.

**4.2 External Activity Time Allowance.** In general, for Covered Persons with a faculty appointment, guidelines for MSK time allocation is as follows:

- 80 percent MSK Institutional Responsibilities;
- 10 percent vacation or paid time off;
- 10 percent outside activities related to MSK Institutional Responsibilities.

This means that in general, no greater than 25 business days per year should be used for outside activities related to an individual's Institutional Responsibilities. The percentage of time for outside activities could be increased by using vacation or other paid time off for the outside activities. Please note that participation in U.S. governmental agency committees or activities with non-profit professional associations related to one's area of clinical or scientific expertise are considered part of one's Institutional Responsibilities and are not considered outside activities for the purposes of this Policy.

**4.3 Review Process.** Combined outside activities exceeding 10 percent of an employee's time are subject to further review by Compliance and the COIC. Upon review, in some cases where the totality of outside commitments exceeds the time allowance for outside activities or the totality of activities appears excessive, questions of potential conflict of commitment will be discussed with the Covered Person and, if needed, the Covered Person's immediate supervisor. Determinations of Conflict of Commitment, and the need for a Covered Person to eliminate or reduce certain outside activities, will be made in coordination with the Covered Person's immediate supervisor and department leadership.

## 5. Conflict of Interest Disclosure

Covered Persons are required to disclose, to MSK, Financial Interests and Outside Activities and Interests that relate to their Institutional Responsibilities. Covered Persons must disclose interests for themselves and any Immediate Family Members.

### 5.1 When to Disclose:

- Upon initial hire;
- Within 30 days of acquiring a new Significant Financial Interest;
- Within 30 days of newly becoming a Covered Person by virtue of position or role; and
- At least annually, even if attesting to no change from previous disclosures.

The formal annual disclosure process launches once each year and requires disclosure of Financial Interests and Outside Activities and Interests that exist at the time of disclosure and/or existed in the previous calendar year.



Compliance formally launches the annual disclosure process to all Covered Persons on an annual basis.

Disclosure may also be required by MSK committees or departments at the time of certain reviews or transactions, if one has related Financial Interests associated with the review or transaction (e.g., at the time of review of a research protocol if one serves on the Research Council, at the time of a purchasing decision when a new vendor is requested).

## 5.2 What to Disclose:

### Financial Interests

Financial Interests include any of the following interests of a Covered Person or an Immediate Family Member related to the Covered Person's Institutional Responsibilities:

- **Ownership/Equity Interests.** Stock, stock options, and other ownership or equity interests in publicly traded and non-publicly traded entities, regardless of value.

*This excludes (i.e., do not disclose) ownership or equity interests through personal retirement accounts, mutual funds, or other diversified investment vehicles to the extent that the Covered Person does not control investment decisions.*

- **Compensation.** Any remuneration for services, such consulting fees, advisory board compensation, honoraria, speaking fees, and paid authorship from for-profit and not-for-profit entities.

*This excludes (i.e., do not disclose) salary or other remuneration paid by/through MSK, or remuneration for seminars, lectures, or teaching engagements sponsored by, or from service on advisory committees or review panels for, U.S. federal, state, or local government agencies; U.S. institutions of higher education; U.S. academic teaching hospitals; U.S. medical centers; or U.S. research institutes affiliated with U.S. institutions of higher education.*

- **Executive Officer Role.** A role at an outside entity that carries with it a fiduciary duty to the entity and/or holds with it the responsibility to make business decisions on behalf of the entity — such as Chief Executive Officer (CEO), Chief Scientific Officer (CSO), Chief Operating Officer (COO), or Chief Financial Officer (CFO) — and serving as a member on a board of directors. Disclosure of executive officer roles is required regardless of whether compensation is received.

- **Intellectual Property Rights and Interests (IP).** Intellectual property rights and interests relating to patents or copyrights upon receipt of income related to such rights and interests. Also included (and required to be disclosed) are intellectual property rights and interests relating to patents or copyrights — regardless of whether income has been received — in any case where the technology underlying the patent or copyright is the subject of a Covered Person's research at MSK.

- **Sponsored/Reimbursed Travel.** Any direct reimbursements (if an entity reimbursed the Covered Person directly) or coverage of costs (if an entity handled the costs without paying or reimbursing the Covered Person) for travel-related expenses (e.g., transportation, lodging, out-of-pocket expenses) associated with outside activities (e.g., consulting, speaking).

*This excludes (i.e., do not disclose) travel paid for by/through MSK, or paid for by/through a U.S. federal, state, or local government agency; a U.S. institution of higher education; a U.S. academic teaching hospital or medical center; or a U.S. research institute affiliated with a U.S. institution of higher education.*

*Note: Disclosure of sponsored/reimbursed travel is required only for Covered Persons who are Investigators on research funded by the PHS (Public Health Service, which includes the National Institutes of Health, the National Cancer Institute, etc.)*

### **Foreign Support**

Any of the following types of support that do not meet the categories above provided to a Covered Person directly from any foreign (non-U.S) government; any organization owned, controlled, or financed in whole or in part by a foreign government; or any foreign institution of higher education and/or research institute or medical center affiliated with a foreign institution of higher education also requires disclosure:

- Grants, awards, or other research funding;
- Laboratory supplies, equipment, or space;
- Research support staff;
- Faculty appointment;
- Personal gifts or support (e.g., housing, cars).

*Excluded from disclosure (i.e., do not disclose) are research agreements between outside entities and MSK as an institution (for example, do not disclose if a foreign university has awarded a grant to MSK on which a Covered Person serves as the MSK Principal Investigator; this is not direct support to the Covered Person).*

### **Outside Activities and Interests**

Regardless of whether a Financial Interest exists, outside activities and relationships, even if not compensated and/or not providing personal financial benefit, could present conflict concerns and require disclosure. Outside Activities and Interests incorporate non-financial interests/relationships and include the following:

- Non-compensated provision of services for an outside entity (e.g., consulting, speaking, education, advisory board service, scientific advisory board service, and medico-legal work);
- Intellectual property rights and interests relating to patents or copyrights, regardless of whether income has been received, in any case where the technology underlying the patent or copyright is the subject of a Covered Person's research at MSK.

*This excludes (i.e., do not disclose) non-compensated services provided for/through MSK, or unpaid service performed for U.S. federal, state, or local government agencies; U.S. institutions of higher education; U.S. academic teaching hospitals; U.S. medical centers; or U.S. research institutes affiliated with U.S. institutions of higher education.*

### **New Significant Financial Interests**

If new Significant Financial Interests arise during the year, they must be disclosed within 30 days of acquisition/occurrence; Significant Financial Interests include the following from any single entity during a 12-month period for a Covered Person or a Covered Person's Immediate Family Member:

- Compensation exceeding \$5,000;
- Ownership or equity interests in a publicly traded entity exceeding \$5,000;
- Any ownership or equity interests in a non-publicly traded entity, even if worth \$0 or relative to which the value is unknown (e.g., a start-up or spin-off company);
- Intellectual property rights and interests exceeding \$5,000;
- Sponsored or reimbursed travel exceeding \$5,000 (applies to PHS-funded Investigators only as described above).

*The same exclusions that apply to Financial Interests apply to Significant Financial Interests; do not disclose remuneration or travel paid for by/through MSK, or paid for by/through a U.S. federal, state, or local*





*government agency; a U.S. institution of higher education; a U.S. academic teaching hospital or medical center; or a U.S. research institute affiliated with a U.S. institution of higher education. Do not disclose ownership or equity interests through personal retirement accounts, mutual funds, or other diversified investment vehicles to the extent that the Covered Person does not control investment decisions.*

New Financial Interests and Outside Activities that arise throughout the year that do not meet the criteria for a Significant Financial Interest as detailed immediately above do not need to be disclosed in eDisclosure within 30 days of acquisition/occurrence; in these cases, a Covered Person can update their disclosure with non-Significant Financial Interests at the time of the subsequent annual disclosure. However, the review and approval process detailed in Section 3.3 of this Policy must still be met.

Please note that the requirements relative to what needs to be disclosed do not mean that any and all disclosed interests constitute conflicts; disclosed interests are reviewed to determine whether potential conflicts exist. Also note that Covered Persons who do not have any Financial Interests or Outside Activities and Interests meeting the criteria for disclosure must still complete an online disclosure in eDisclosure when required; this is the documented record of having been asked and having responded to the required questions.

**5.3 Where to Disclose:** Disclosures are made through MSK's online [eDisclosure](#) system.

Additionally, disclosure to MSK committees or departments may be required (e.g., Research Council meeting, Pharmacy and Therapeutics Committee meeting, Procurement) in the manner prescribed by the committee or department.

## 6. Conflict Reviews

Compliance and the COIC, or their designee(s), have the authority to and are responsible for reviewing disclosed Financial Interests and Outside Activities and Interests to determine whether a conflict of interest or conflict of commitment exists in the context of the Covered Person's Institutional Responsibilities.

In reviewing disclosures, MSK considers the nature and extent of a Covered Person's Financial Interests and Outside Activities and Interests in relation to their responsibilities at MSK (e.g., clinical, research, education, training, business, purchasing), considering any actual or perceived bias in MSK decision-making that could arise from related interests. Examples of related interests that could present conflicts include but are not limited to the following when related to an outside entity with which a Covered Person has interests:

- An entity is a vendor or potential vendor of MSK, and the Covered Person is in a position to influence business or purchasing.
- An entity sponsors, funds, or otherwise supports research at MSK in which the Covered Person is directly involved.
- An entity makes a product that is being evaluated in research at MSK in which the Covered Person is directly involved.
- An entity is licensing intellectual property with which the Covered Person has rights.
- Intellectual property relative to which the Covered Person has rights is being evaluated in research at MSK in which the Covered Person is directly involved.
- An entity makes a gift (e.g., unrestricted funds or loaning of equipment) to MSK under the control of or directly in support of the Covered Person's Institutional Responsibilities.
- An entity supports the Covered Person's participation in continuing education activities or professional conferences.
- A Covered Person has the authority to direct the efforts of graduate students, staff, trainees, post-docs, or



others under their supervision at MSK and is conducting research involving a for-profit entity to which their efforts could be directed.

- Outside activities that interfere with or detract from a Covered Person's Institutional Responsibilities (e.g., insufficient attention to MSK responsibilities, such as MSK clinical care or research, mentoring of trainees or students, supervision of staff, administrative responsibilities).
- Excessive or unauthorized use of MSK time or resources for outside activities related to any entity.

MSK must identify and manage, reduce, or eliminate identified Conflicts of Interest or Conflicts of Commitment in the manner detailed in Section 7 of this Policy.

In the case of MSK Senior Executives, in addition to Compliance and COIC review, disclosures are also reviewed by, and determinations made by, the JCOIC.

## 7. Conflict Determinations and Conflict Management

### **Conflict Determinations**

**7.1 COI Determinations.** Compliance and the COIC, or their designee(s), have the authority and are responsible for reviewing disclosed Financial Interests and Outside Activities and Interests to determine whether a Conflict of Interest or Conflict of Commitment exists in the context of a Covered Person's Institutional Responsibilities (e.g., clinical, research, education, training, business, purchasing).

A Conflict of Interest exists when an individual's Financial Interests or Outside Activities and Interests could directly and significantly impact their Institutional Responsibilities, or an individual's Financial Interests or Outside Activities and Interests could be directly and significantly impacted by their Institutional Responsibilities.

If a Conflict of Interest determination is made, MSK must develop conflict of interest management strategies to manage, reduce, or eliminate the conflict. COI Management Plans are strategies designed to mitigate the potential for a Covered Person's related interests to impact or bias applicable Institutional Responsibilities.

**7.2 Conflict of Commitment Determinations.** A Conflict of Commitment exists when an individual's Financial Interests or Outside Activities and Interests interfere with or detract from their Institutional Responsibilities. Conflicts of commitments are handled in consultation with a Covered Person's immediate supervisor and department leadership, and generally result in reduction or elimination of one or more outside activities.

**7.3 COI Determinations Related to Research.** In the case of research, a Financial Conflict of Interest (FCOI) exists when an Investigator has Financial Interests, determined by MSK, that relate to and have the ability to directly or significantly impact or bias the design, conduct, or reporting of research, or create the perception thereof.

In the case of research-related conflicts of interest, MSK's determinations and management strategies must make primary the protection of objectivity in the design, conduct, and reporting of MSK research and the safety and welfare of human research subjects.

**7.4 Human Subjects Research.** When an Investigator has an FCOI related to human subject research, MSK's primary objective must be to ensure that the FCOI does not impinge on the rights and welfare of human subject research participants in the related research.

An FCOI determination for any human subject research must be managed, reduced, or eliminated. Management strategies must be sufficient and appropriate to adequately protect the rights and welfare of human subject





research participants in the related research.

Additionally, a Covered Person will not be permitted to serve as Principal Investigator (PI) or Co-Principal Investigator (co-PI) on an interventional human subject research protocol if the Covered Person has any of the following financial interests *in any one entity sponsoring or supporting the research or otherwise related to the research as noted*, absent compelling circumstances, which will be determined by the COIC, or its designee(s):

- Compensation for services exceeding \$25,000 in the prior 12-month period (e.g., consulting, advisory board, speaking, honoraria);
- Equity interests (e.g., stock, stock options) in a publicly traded entity exceeding \$25,000 in value;
- Any equity interests (e.g., stock options or warrants) in a non-publicly traded entity (e.g., start-up company);
- Any intellectual property interests to which the Covered Person has rights (e.g., inventor) when the intellectual property is being tested, evaluated, or further developed in the research;
- Holding an Executive Officer role.

The COIC, or its designee(s), may consider compelling circumstances that may allow a Covered Person to serve as a PI or Co-PI in the related interventional human subjects research in cases where the above-noted interests exist. The following factors will be considered when determining whether compelling circumstances exist:

- Specialized or unique experience and/or expertise of the conflicted Covered Person related to the research;
- Risk level to the human subjects, including whether the specialized experience and expertise of the conflicted Covered Person is such that the safety and welfare of the human subjects are best served if that individual participates in the research, despite the conflict;
- Research structure and study design, including aspects that could serve as potential controls (e.g., multi-site, blinded, external data safety monitoring board);
- Correlation between the related interests and the aims of the research;
- Specific role and responsibilities of the conflicted Covered Person in the research.

If compelling circumstances are demonstrated and a conflicted Covered Person is permitted to remain engaged in interventional human subject research as PI or co-PI under a Management Plan, the COIC may define limits on any external compensation that may be received during the course of a research study where applicable, and/or impose other limits or actions related to financial interests during the course of the research.

In any case that a conflicted Covered Person is permitted to be involved in any human subject research, in any role, the research will be conducted under robust management strategies to protect the rights and welfare of human research subjects as well as the objectivity and integrity of the research.

## **Conflict Management**

**7.5 COI Management Plans.** If Compliance or the COIC, or their designee(s), determines that a COI or FCOI exists that can be managed, a Management Plan will be developed and implemented.

Management Plans are strategies implemented by MSK to mitigate Conflicts of Interest and Financial Conflicts of Interest by setting parameters around the related interests or activities and the Covered Person's impacted Institutional Responsibilities. Management Plans must be implemented prior to the initiation of the activity for which the conflict exists, and Covered Persons subject to a Management Plan must acknowledge and agree in writing to the terms of the Management Plan.



Any or all of the following may be included as terms in a Management Plan; this is a non-exhaustive list and alternative or additional terms may be included at the recommendation of Compliance or the COIC, or their designee(s), to address a specific COI or FCOI:

- Disclosure of the related interest(s) to the following, *as applicable*
  - Staff under a Covered Person's supervision or mentorship;
  - Research project team members and collaborators;
  - Research subjects;
  - Patients.
- Disclosure of the related interest(s) in presentations, publications, manuscripts, and press releases;
- Recusal or limitation in role, such as
  - Recusal from business or purchasing decisions;
  - Prohibition or limit on involvement in (or independent involvement) in research data collection or analysis, human research subject recruitment, enrollment and/or consent activities, performing certain research interventions or procedures, and/or involvement in adverse event evaluation and reporting;
  - Prohibition on serving as the Principal Investigator or Co-Principal Investigator;
  - Prohibition or limitations on serving as the treating physician on related single-patient-use treatment plans.
- Oversight of activity (e.g., research) by a neutral internal or external third party (e.g., an independent individual or oversight committee);
- Specific limitations on new or additional Financial Interests or activities with the related entity (e.g., prohibition or limit in external compensation from a related entity during the course of related research).

**7.6 Oversight Committee.** The COIC will determine whether the risk of bias in research data resulting from FCOIs should be mitigated by periodic reviews by subcommittees established by the COIC, composed of representative faculty and staff. Any requirement for this level of oversight and review will be included in the terms of the Management Plan.

**7.7 Laboratory Research.** Regardless of specific Management Plans implemented by Compliance or the COIC, or their designee(s), Covered Persons with a COI or FCOI must disclose to others working in the lab, or who are collaborating on a research project, any outside Financial Interest in a healthcare, biomedical, scientific, or technology company that could affect or be affected by the research being conducted; the nature of any sponsored awards or other research support received from such companies, including its specific scope of work and the time and effort allocations applicable to those persons; and financial interests to the thesis or related committees of any graduate students working in the lab.

**7.8 Involvement and Engagement of MSK's Institutional Review Board (IRB).** While Compliance and the COIC, or their designee(s), have the authority and responsibility for COI and FCOI determinations and the institution of Management Plans, the IRB has a responsibility and authority to ensure that any Management Plan adequately protects the rights and welfare of human research participants in related research, and may require that more stringent management strategies be instituted. Compliance provides the IRB with final executed copies of all Management Plans related to human subject research. The IRB has the final authority to determine whether a COI or FCOI is sufficiently managed to allow related human subject research protocols to be approved by the IRB.

**7.9. Institutional Committees.** In order to protect the objectivity and integrity of MSK clinical, research,



educational, business, and procurement reviews and decisions, Institutional Committees must have processes in place to address the related Financial Interests of Covered Persons serving on the committee. These processes must include but are not limited to the following elements:

- Requiring disclosure to the committee members, as appropriate, at the time that the committee makes a decision relating to a Covered Person's Financial Interests;
- Requiring recusal of a Covered Person from deliberation and decision-making related to their Financial Interests, as appropriate;
- Ensuring that any actions taken by the committee regarding conflict matters be reflected, as appropriate, in the minutes or other records of the committee's proceedings;
- Ensuring that the committee's conflict procedures apply to both members of the committee and other individuals who may participate in committee deliberations and decision-making.

**7.10 Appeals.** If a Covered Person disagrees with a decision regarding a conflict determination, the individual may appeal the determination to Compliance. All appeals must be made in writing within 15 calendar days of the individual's receipt of the conflict determination.

## 8. External and Public Disclosures

**8.1 External Disclosures.** Regardless of the disclosure requirements outlined in this Policy or additional disclosure strategies instituted by MSK in Management Plans, each Covered Person is responsible for being transparent with respect to their Financial Interests and Outside Activities and Interests in all matters, internal and external to MSK, related to their Institutional Responsibilities. This includes but is not limited to ensuring to disclose completely and accurately in accordance with the disclosure requirements of journals, conference or meeting conveyers, professional associations, government agencies, and continuing medical education providers. If there is any doubt as to whether or not a Covered Person's Financial Interests and/or Outside Activities and Interests should be disclosed in a particular instance because of a relevance standard, Covered Persons should err on the side of disclosure.

**8.2 Public Disclosure.** In the interest of openness and transparency, MSK will make publicly available via its website Financial Interests and Outside Activities and Interests of Covered Persons meeting certain criteria, including financial interests related to entities in the healthcare, biomedical, scientific, and technology industries. This also includes Financial Interests in entities that make products used in patient care. Information populating the public-facing disclosures will come from a Covered Person's annual disclosure in MSK's eDisclosure system. Compliance is responsible for ensuring that the public information is refreshed on an annual basis.

## 9. Conflict of Interest Training

All Covered Persons are required to complete conflict of interest training at least every two years. The training module is completed online through MSK's centralized learning management system (LMS). LMS provides electronic notification to Covered Persons who are subject to and due to take the training. Compliance monitors Covered Persons' compliance with COI training requirements.

## 10. Additional Considerations Related to PHS-Funded Research

**10.1 Disclosure.** Investigators must have a current disclosure on file with MSK prior to the time of application to PHS for research or within 30 days of newly becoming an Investigator on PHS-funded research. PHS-funded Investigators are required to meet all disclosure requirements specified in Section 5 of this Policy, including the disclosure of sponsored and reimbursed travel (which applies to PHS-funded researchers only).

**10.2 Training.** COI training requirements specified in Section 9 must be met prior to engaging in research, within



30 days of newly becoming an Investigator on PHS-funded research, and every two years. COI training must also occur promptly in certain cases as designated by Compliance (e.g., significant policy changes, non-compliance). For Investigators on PHS-funded research, failure to complete required training, or having an expired training date, impacts their ability to participate in research and could impact funding for any research project on which the Investigator is involved.

**10.3 Reporting of FCOIs to PHS Agencies.** When an FCOI is found to exist for an Investigator involved in PHS-funded research, MSK is required to provide the funding agency with an FCOI report that includes specific information on the nature of the FCOI and how MSK is managing the FCOI. The report must be submitted to the funding agency prior to MSK's expenditure of any funds under a PHS-funded research project; an annual FCOI report is required thereafter. For any new FCOI identified during an ongoing PHS-funded research project (e.g., a new Significant Financial Interest for an Investigator or the participation of a new Investigator with an FCOI), MSK shall implement a Management Plan and submit the required FCOI report to the funding agency within 60 days of identification.

**10.4 Retrospective Reviews.** For PHS-funded research, whenever an FCOI is not identified or managed in a timely manner, including failure by an Investigator to make a complete or timely disclosure, failure of MSK to identify or manage an FCOI, or failure of an Investigator to comply with the conditions of a Management Plan, MSK must conduct a retrospective review of the Investigator's research activities on the project for which the FCOI applied to determine if there was bias in the design, conduct, or reporting of the research resulting from the FCOI. The retrospective review must be completed within 120 days of the determination of non-compliance. If bias is found in the course of the retrospective review, MSK must promptly notify the funding agency and submit a mitigation report that addresses the impact of the bias on the research and MSK's plan of action to eliminate or mitigate the effect of the bias. Additionally, for instances of non-compliance noted above involving PHS-funded clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, the Investigator is thereafter required to disclose the FCOI in each public presentation of the results of the relevant research and also request an addendum to previously published presentations of the relevant research.

**10.5 Public Accessibility of FCOI Information related to PHS-Funded Research.** MSK is required to make available to the public, upon request, specific information regarding FCOIs determined for senior and key personnel relative to PHS-funded research. MSK is required to provide specific information relative to such public requests within five business days of the request.

Requests for information must be made in writing to MSK's Compliance Officer at the following address:

Chief Risk Officer  
Memorial Sloan Kettering Cancer Center  
1275 York Avenue Box 705  
New York, NY 10065

Compliance will respond to such requests within five business days of receipt.

**10.6 Record Retention.** Records relative to PHS research-related COI matters covered under this Policy must be maintained for a period of three years after any applicable research project's final financial report is submitted to the funding agency, or until three years after the final action has been taken on any audit, litigation, or claim.

## 11. Monitoring and Auditing

Compliance will routinely monitor and audit compliance with the conditions of this Policy and other COI-related policies. Compliance will conduct regular and scheduled audits using both risk-based and random approaches



in its efforts to:

- Verify the accuracy of disclosures of Covered Persons' Financial Interests and Outside Activities and Interests to MSK in compliance with this Policy;
- Assess Covered Persons' compliance with Management Plans, including the review of relevant documentation (e.g., publications, presentations, research consent forms, notifications to laboratory members and research staff and collaborators), and interviews with persons subject to the Management Plan and representative colleagues, research staff, and/or lab team members);
- Verify the completeness and accuracy of Covered Persons' disclosures in publications and presentations.

Compliance will utilize external and/or publicly available information to compare a Covered Person's disclosures to MSK in the interest of verifying the completeness and accuracy of disclosures.

Compliance will work with Covered Persons and the MSK community in its monitoring and compliance activities in an effort to educate and support in a proactive manner.

## 12. Roles and Responsibilities

**A. Covered Persons.** Covered Persons (as defined in this Policy) are those individuals subject to the training, disclosure, and other requirements outlined in this Policy, and are required to comply with all applicable requirements outlined in the Policy.

**B. 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 the JCOIC. Compliance is responsible for supporting and providing guidance to Covered Persons in COI-related matters.

**C. 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.

**D. Joint Conflict of Interest Committee (JCOIC).** The JCOIC is a 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.

## 13. Compliance and Enforcement

Covered Persons 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 a 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.

## 14. Definitions

**Conflict of Commitment:** A conflict of commitment exists when a Covered Person's Financial Interests or Outside Activities and Interests interfere with or detract from their Institutional Responsibilities.

**Conflict of Interest:** A conflict of interest exists when a Covered Person's Financial Interests or Outside Activities and Interests could directly and significantly impact their Institutional Responsibilities, or an individual's Financial Interests or Outside Activities and Interests could be directly and significantly impacted by their Institutional Responsibilities.

**Covered Person:** Those individuals subject to the disclosure and other requirements specified in this Policy, which includes:

- Physicians and scientists with academic appointments at any level;
- Any clinical provider who can independently write orders or prescriptions (e.g., physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists);
- Individuals responsible for the design, conduct, or reporting of research and/or those who are engaged in human subject research, regardless of level or title (e.g., fellows, post-doctoral researchers, graduate students, clinical research nurses); this could include individuals that are not employees of MSK;
- Administrative positions with independent authority to make purchasing decisions or otherwise bind, negotiate on behalf of, or execute agreements for MSK, which includes:
  - Employees in any department at a management level 4 and above;
  - Exempt (salaried) employees at any level in the following departments: Compliance and Internal Audit, Development, Facilities, Finance, General Counsel, Investments, Research and Technology Management, Procurement.
- Individuals, regardless of level or title, whether internal or external to MSK, that serve on MSK institutional committees with responsibility for oversight of research, formulary, or purchasing decisions (e.g., Institutional Review Board, Pharmacy and Therapeutics Committee, Value Analysis Committee).

**Disclosure (or Disclose):** Disclosure is the mechanism for Covered Persons to communicate specific information about their Financial Interests and Outside Activities and Interests.

**Financial Conflict of Interest (FCOI):** An FCOI exists when an Investigator has Significant Financial Interests, determined by MSK, that relate to and have the ability to directly or significantly impact or bias the design, conduct, or reporting of research, or create the perception thereof.

**Financial Interest (FI):** Financial Interests include the following from any single entity during a disclosure period for a Covered Person or a Covered Person's Immediate Family Members:

- **Ownership/Equity Interests.** Stock, stock options, and other ownership or equity interests in publicly traded and non-publicly traded entities, regardless of value.
- **Compensation.** Any remuneration for services, such consulting fees, advisory board compensation, honoraria, speaking fees, and paid authorship from for-profit and not-for-profit entities
- **Executive Officer Role.** A role at an outside entity that carries with it a fiduciary duty to the entity and/or



holds with it the responsibility to make business decisions on behalf of the entity, such as Chief Executive Officer (CEO), Chief Scientific Officer (CSO), Chief Operating Officer (COO), Chief Financial Officer (CFO), and serving as a member on a board of directors. Disclosure of executive officer roles is required regardless of whether or not compensation is received.

- **Intellectual Property Rights and Interests (IP).** Intellectual property rights and interests relating to patents or copyrights upon receipt of income related to such rights and interests. Also included (and required to be disclosed) are intellectual property rights and interests relating to patents or copyrights — regardless of whether income has been received — in any case where the technology underlying the patent or copyright is the subject of a Covered Person’s research at MSK.
- **Sponsored/Reimbursed Travel.** Any direct reimbursements (if an entity reimbursed the Covered Person directly) or coverage of costs (if an entity handled the costs without paying or reimbursing the Covered Person) for travel-related expenses (e.g., transportation, lodging, out-of-pocket expenses) associated with outside activities (e.g., consulting, speaking).

*Excluded from FI: ownership or equity interests through personal retirement accounts, mutual funds, or other diversified investment vehicles to the extent the Covered Person does not control investment decisions, and remuneration or travel paid for by/through MSK, or paid for by/through a U.S. federal, state, or local government agency; a U.S. institution of higher education; a U.S. academic teaching hospital or medical center; or a U.S. research institute affiliated with a U.S. institution of higher education.*

**Institutional Committee:** An MSK committee with responsibility for the oversight of research, formulary, or purchasing decisions (e.g., COIC, Institutional Review Board, Pharmacy and Therapeutics Committee, Value Analysis Committee).

**Immediate Family Member:** A Covered Person’s spouse, domestic or civil union partner, and dependent children.

**Institutional Responsibilities:** A Covered Person’s professional responsibilities on behalf of MSK, including activities such as clinical care, research, research consultation, teaching, professional practice, Institutional Committee membership, business and purchasing decisions, and mentoring or supervision of trainees, graduate students, and post-docs.

**Investigator:** A project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of MSK research.

**Management Plan:** Strategies implemented by MSK to mitigate Conflicts of Interest and Financial Conflicts of Interest by setting parameters around the related interests or activities and the Covered Person’s impacted Institutional Responsibilities.

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

**Outside Activities and Interests:** Regardless of whether a Financial Interest exists, outside activities and relationships, even if not compensated and/or not providing personal financial benefit, could present conflict concerns and require disclosure. Outside Activities and Interests incorporate non-financial interests/relationships and include the following:

- Non-compensated provision of services for an outside entity (e.g., consulting, speaking, education, advisory board service, scientific advisory board service, and medicolegal work);
- Intellectual property rights and interests relating to patents or copyrights, regardless of whether income has been received, when the technology underlying the patent or copyright is the subject of a Covered Person’s



research at MSK.

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

**Significant Financial Interest (SFI):** Significant Financial Interests include the following from any single entity during a 12-month period for a Covered Person or a Covered Person's Immediate Family Member:

- Compensation exceeding \$5,000;
- Ownership or equity interests in a publicly traded entity exceeding \$5,000;
- Any ownership or equity interests in a non-publicly traded entity, even if worth \$0 or relative to which the value is unknown (e.g., a start-up or spin-off company);
- Intellectual property rights and interests exceeding \$5,000;
- Sponsored or reimbursed travel exceeding \$5,000 (applies to PHS-funded Investigators).

*Excluded from SFI: ownership or equity interests through personal retirement accounts, mutual funds, or other diversified investment vehicles to the extent that the Covered Person does not control investment decisions, and remuneration or travel paid for by/through MSK, or paid for by/through a U.S. federal, state, or local government agency; a U.S. institution of higher education; a U.S. academic teaching hospital or medical center; or a U.S. research institute affiliated with a U.S. institution of higher education.*

**Spin-Off:** An MSK Spin-Off company means a for-profit company funded by MSK and/or largely driven by intellectual property licensed from MSK.

## 15. 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. Interactions with Industry Policy
- C. [Institutional Conflict of Interest Policy](#)
- D. Endorsements Policy
- E. Policy on Intellectual Property
- F. Authorship Guidelines