I. INTRODUCTION

The mission of Memorial Sloan Kettering Cancer Center (hereinafter "MSK") is the progressive control and cure of cancer through programs of patient care, clinical and laboratory research, education, and training. MSK encourages its staff to participate in outside activities that further its mission and promote the practical application of scientific discoveries. Although this collaboration provides individual, institutional, and societal benefits, it can give rise to competing and possibly conflicting interests that may compromise–or appear to compromise–the integrity and objectivity of research, education, clinical judgment, and purchasing decision-making. We recognize that MSK's staff has a unique opportunity to improve and advance patient care through collaboration with industry. Because conflicts of interest can undermine public trust in our work, the Institution has adopted this Policy to identify and manage situations that may give rise to conflicts.

This Policy promotes intellectual honesty and objectivity in scientific research; transparency in dealings with outside organizations and business partners; and accountability to all stakeholders, including patients, human research subjects, research sponsors, MSK staff, the federal government and the public.

With regard to Conflict of Commitment (as defined below), this Policy is based on the premise that, as employees each staff member's primary professional responsibility is to the MSK. To fulfill that responsibility, employees are expected to conduct outside activities in a way that allows them to devote their energies to activities that further the academic and patient care objectives of MSK.

This Policy applies to outside activities, whether compensation is received or not, that create or reasonably appear to create a conflict of interest or conflict of commitment.

II. DEFINITION OF TERMS

A. A **Conflict of Commitment** arises when the amount of time or effort a Covered Person devotes to outside activities significantly interferes with the Covered Person's ability to fulfill his or her Institutional Responsibilities. Conflicts of Commitment may also arise when an employee's outside activities conflict with the obligations set forth in the MSK Code of Conduct or if the activities create a fiduciary responsibility to another organization, which interferes with the employee's MSK Institutional Responsibilities.

B. **Conflict of Interest Advisory Committee (COIAC)** is the standing body appointed by the President of MSK that is responsible for reviewing and adjudicating, in accordance with the process set forth in this Policy, situations in which a Covered Person is engaged in an outside activity that may be in conflict with any of his or her job duties, as set forth in this Policy. The Committee is responsible for reviewing all relevant facts and making recommendations to the President regarding whether a Financial Conflict of Interest exists and, if so, how best to manage any such conflict. The COIAC is charged with the responsibility to review this Policy periodically and make recommendations for revisions to the President. The COIAC may include at least one member who is also a current member of MSK's Institutional Review Board (IRB) or has served on the IRB. In addition, the COIAC may include at least one member from outside MSK.

C. **Covered Person** means any full- or part-time MSK employee in any of the following job categories: physicians and scientists with academic appointments at any level, fellows and postdoctoral researchers; administrative positions that have the authority to make Purchasing Decisions or are otherwise able to bind, negotiate on behalf of, or execute agreements for MSK; and any other person, regardless of title or position whose responsibilities include the activities set forth below in this Section C. Covered Person also includes

certain non-employees, as may be designated by MSK, who are Senior/Key Personnel on Public Health Service (PHS)-funded research as well as employees and non-employees whose jobs include the following responsibilities:

1. The design, conduct, or reporting of research;
2. The authority to influence Purchasing Decisions as part of their routine job duties, as well as those who are assigned this authority as members of committees.

D. Designated Officials means the officials designated by MSK who are responsible for soliciting and reviewing Disclosures of Financial Interests and potential Conflicts of Commitment from Covered Persons. MSK has designated the Chair of the Conflict of Interest Advisory Committee and the Compliance Officer as such officials.

E. Disclosure (or Disclose) means the Covered Person's communication of specific information about Financial Interests or potential Conflicts of Commitment to MSK.

1. **Prior Approval** means disclosing and obtaining approval for a Financial Interest or potential Conflict of Commitment before it is acquired.
2. **Timely Disclosure** means disclosing a Financial Interest as soon as possible and no later than 30 days from its acquisition or discovery.

F. Family Members means a Covered Person's spouse and dependent children.

G. A **Financial Conflict of Interest (FCOI)** exists if MSK reasonably determines that the Financial Interest could directly and significantly affect the design, conduct, or reporting of the research; the outcome of Purchasing Decisions; or the supervision or mentoring of trainees.

H. Financial Interest (FI) means any of the financial interests defined below that can reasonably appear to be related to the Covered Person's Institutional Responsibilities:

1. **Equity Interests Held by Covered Persons.** This includes stock, stock options, and other ownership interests in publicly traded and non-publicly traded entities during the 12 months preceding the Disclosure, regardless of value. This excludes stock held in investment vehicles in which the Covered Person does not directly control investment decisions, such as mutual funds or retirement accounts.
2. **Compensation Received by Covered Persons**. This includes remuneration such as salary, consulting fees, honoraria**,** and paid authorship, both from for-profit and not-for-profit organizations, and compensation received from foreign institutions and governments of other countries, received during the 12 months preceding the Disclosure. Compensation does not include: salary or other remuneration paid by MSK or income from 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. The Disclosure must include all Compensation received by a Covered Person, regardless of its value.
3. **Equity Interests Held by and Compensation Received by Family Members**. The definitions of Equity Interests and Compensation for Covered Persons apply to Family Members, except for the threshold for Disclosure, as follows: With regard to any publicly traded entity, Disclosure is required if the value of any remuneration received from the entity in the 12 months preceding the Disclosure and the value of any Equity Interest in the entity as of the date of Disclosure, when aggregated, exceeds $5,000. With regard to any non-publicly traded entity, Disclosure is required if the value of any remuneration received

from the entity in the 12 months preceding the Disclosure, when aggregated, exceeds $5,000 or when the Family Member holds any Equity Interest in the entity. The specific value of a Family Member's Compensation and Equity Interests is not required in the Disclosure.

4. **Intellectual Property Rights and Interests (IP)**. This includes intellectual property rights and interests relating to patents or copyrights held by a Covered Person or his/her Family Member which are considered to be a Financial Interest upon receipt of income related to such rights and interests. The term shall also include intellectual property rights and interests relating to patents or copyrights held by a Covered Person or his/her Family Member regardless of whether income has been received, in any case where the technology underlying the patent or copyright is the subject of human subject research conducted at MSK and the Covered Person is involved in the research.
5. **Travel** means reimbursed or sponsored travel expenses that are related to an Investigator's Institutional Responsibilities, including travel paid for by non-U.S. institutions and governments of other countries. Disclosure of reimbursed or sponsored travel is required for Investigators working on PHS-funded research. Excluded from this definition is travel paid for by MSK or a 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.
6. **Executive or Management Role** means a role at an outside entity that carries with it a fiduciary duty (e.g., service on a board of directors or as a CEO) or the responsibility to make business decisions on behalf of the outside entity that could reasonably impact the conduct of the Covered Person's Institutional Responsibilities (e.g., purchasing or service contracting arrangements that relate to MSK business). Executive or Management Roles at for-profit companies may create a Conflict of Commitment, regardless of whether compensation is provided.

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

J. **Institutional Committee** means the Pharmacy and Therapeutics Committee and other purchasing committees, the IRB, and the Research Council.

K. **Institutional Responsibilities** means a Covered Person's professional responsibilities on behalf of MSK, including activities such as research, research consultation, teaching, professional practice, Institutional Committee membership, service on other panels such as the Data and Safety Monitoring Committee, participation in Purchasing Decisions, and mentoring or supervision of trainees.

L. **Intellectual Property Rights and Interests (IP).** See Financial Interest**.**

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

N. A **Management Plan** defines the action(s) taken by MSK to address a Financial Conflict of Interest or Conflict of Commitment.

O. **Purchasing Decisions** means the selection of vendors or products on behalf of MSK, and includes contract negotiation relating to such purchases, or decisions to continue or expand business with a given company.

P. **Related.** A Covered Person's Financial Interest is Related to research, Purchasing Decisions, or supervision of trainees if MSK reasonably determines that the Financial Interest could be affected by such duties, or is in an entity whose financial interests could be affected by such duties. MSK may involve the Covered Person in making this determination.

Q. Senior/Key Personnel means the project director/principal Investigator or any other person identified as senior/key personnel by MSK in the grant application, progress report, or any other report submitted to the PHS by MSK in accordance with 42 CFR Part 50 Subpart F (hereinafter the PHS regulations).

R. Significant Financial Interest (SFI). MSK adheres to the PHS definition of SFI, which includes the following:

1. Ownership interest (e.g., shares, partnership stake, stock options) of any amount in a privately-held entity;
2. Ownership interest (e.g., shares, partnership stake, stock options) of $5,000 or more in a publicly-traded entity;
3. Income amounting to $5,000 or more per year per entity, including payments for services, consulting fees, honoraria, etc.;
4. Any combination of the above financial interests in a single entity that amount to $5,000 or more in aggregate in the prior 12 months;
5. Intellectual property rights and interests, upon receipt of income related to such rights and interests.

III. POLICY ON CONFLICT OF INTEREST

A. Covered Persons are required to disclose outside activities and FIs that reasonably appear to be related to the Covered Person's Institutional Responsibilities; this includes outside activities for which there is no remuneration. Investigators working on research projects funded by a PHS agency are required to Disclose Travel, in addition to the other FIs identified in this Policy.

B. Disclosure includes timely disclosure for all activities and Prior Approval for certain activities where there is an FI (see Section IV and Appendix 1 for information on disclosure requirements for outside activities). Disclosure is required at the time of initial employment. In addition, annually, all Covered Persons are required to certify that their Disclosures are complete and accurate. With respect to Disclosures relating to PHS-funded research, such Disclosures shall be made no later than at the time of application for such funding. Disclosure of FIs may also be required by Institutional Committees at the time of certain transactions, including, for example, at the time of submission of clinical research protocol to the Research Council or at the time Purchasing Decisions are made.

C. MSK is responsible for making a determination as to whether the FI is Related to research, Purchasing Decisions, or supervision of trainees that involve the Covered Person. MSK may consult with the Covered Person to make this determination, but responsibility for the final decision regarding Relatedness rests with MSK. All records relating to disclosures will be maintained for three years from the date the final expenditures report is submitted to the PHS or longer where required by law.

D. If an FI is found to be Related to research, Purchasing Decisions, or supervision of trainees that involve the Covered Person, MSK is solely responsible to determine if the FI is Significant and creates an FCOI.

E. If an FCOI is determined by MSK to exist, MSK is responsible for determining how to eliminate or manage the conflict. A Management Plan is implemented for all FCOIs. For PHS-funded research in which an FCOI exists, MSK is required to provide a report on the Management Plan to the PHS funding agency (see Subsection VI.E.) and to provide for public access to certain information about the FCOI (see Subsection VI.F.). If an FCOI is not identified or managed in a timely manner, a retrospective review will be conducted (see Subsection VI.G.).

F. All Covered Persons are periodically required to complete conflict of interest training. The content of the training is maintained by the Compliance Office. Investigators working on PHS-funded research are required to complete training prior to engaging in research related to any PHS-funded grant. In addition, investigators working on PHS-funded research are required to complete conflict of interest training every four years or at the time of any of the following: a) immediately when MSK revises this Policy in such a way that it affects requirements of investigators, b) an Investigator is new to MSK, or c) an Investigator is not in compliance with this Policy or a Management Plan. The training module is completed online through MSK's centralized learning management system (LMS). LMS provides electronic notification to Covered Persons who are due to take the training. The system also tracks completion of training.

IV. DISCLOSURE OF FINANCIAL INTERESTS *(See Appendix 1 for a Summary of Disclosure Requirements)*

A. Disclosure is required at the time any employee or non-employee becomes a Covered Person. This includes new hires into positions covered by this Policy as well as staff that transfer or are promoted into such positions. When making an initial Disclosure, the Covered Person must report Compensation earned in the prior 12 months, sponsored Travel from the prior 12 months, any Equity Interest, and Intellectual Property.

B. Thereafter, Covered Persons must:

1. Seek Prior Approval before acquiring Equity Interests and before earning Compensation from for-profit entities. In cases where there is a contract to review relating to Compensation, submission of the contract to MSK should allow time for this review prior to the start date of the activity;
2. Make timely disclosure of the Covered Person's Compensation from not-for-profit organizations, foreign institutions, and governments of other countries;
3. Make Timely Disclosure of a Family Member's Compensation and Equity Interests;
4. Make Timely Disclosure of the Covered Person's and his/her Family Member's non-MSK IP;
5. PHS-funded Investigators are required to disclose Travel (see Section II.H.5) sponsored or reimbursed by outside organizations. Travel disclosures must include the following information: sponsor/organizer; destination; duration; and purpose of the trip.
6. Annually certify that Disclosures are complete and up-to-date.

C. Disclosures must be made to the Compliance Department through the COI disclosure web application, and to Institutional Committees as required by such Committees.

D. Institutional Committees must have processes in place to address FIs. These processes must include, but are not limited to, the following elements:

1. Requiring disclosure to the Committee, as appropriate, at the time that the Committee makes a decision relating to a Covered Person's FI;
2. Requiring recusal of a Covered Person from deliberation and decision-making, as appropriate;
3. Ensuring that any actions taken by the Committee regarding FIs be reflected, as appropriate, in the minutes or other records of the Committee's proceedings; and
4. Ensuring that the Committee's policies regarding FIs apply to both members of the Committee and other Covered Persons who may participate in Committee deliberations and decision-making.

V. ADJUDICATION, MANAGEMENT, AND REPORTING OF FINANCIAL CONFLICTS OF INTEREST

A. Determination of Relatedness. The Designated Officials and their designees are authorized to determine whether an FI reasonably appears to be related to a Covered Person's research, Purchasing Decisions, or supervision of trainees, and to identify cases that require review by the COIAC. Criteria MSK may use to determine whether an FI is reasonably Related to Institutional Responsibilities include, but are not limited to, the following:

1. The entity sponsors, funds, or otherwise supports research at MSK in which the Covered Person is directly involved;
2. The Covered Person's FI are such that they could reasonably be considered to have a potential influence on the design, conduct, or reporting of the research;
3. The entity makes a product that is being studied in research in which the Covered Person is directly involved;
4. The entity makes gifts (including loaning of equipment) to MSK which will be under the control of or will directly support the Covered Person's Institutional Responsibilities;
5. The entity licenses MSK IP in which the Covered Person has an FI;
6. The entity supports the Covered Person's participation in continuing education activities or professional conferences.

The Designated Officials or their designees will review all Disclosed FI to determine Relatedness. If a Related FI is of an amount determined to be Significant, MSK will determine if the Significant Financial Interest (SFI) constitutes a Financial Conflict of Interest (FCOI). All Related FIs are subject to the Transparency Standard described in **Section V.D.** of this policy, regardless of whether they are determined to be a SFI or FCOI.

B. Determining Whether an FCOI Exists. The COIAC will review Related SFIs and determine whether they constitute an FCOI; e.g., if the SFI could directly and significantly affect the design, conduct, or reporting of research; the outcome of Purchasing Decisions; or the supervision or mentoring of trainees.

The Designated Officials may make a determination of FCOI and approve activities or Management Plans when the COIAC has previously approved cases with substantially similar fact patterns. The Designated Officials will periodically report to the COIAC the dispositions of any such actions.

1. **Research.** When a Covered Person is an Investigator and the Covered Person or his/her Family Member has an SFI that is determined to be Related to the Investigator's research**,** the COIAC or Designated Officials will determine whether an FCOI exists. To make this determination, the COIAC or Designated Officials will consider all relevant facts, including, but not limited to: the risk of harm to human subjects; the design of the research, including aspects of the design that could serve as controls on a potential conflict of interest (e.g., whether the research involves multiple centers); the relationship between the SFI and the aims of the research; and the role of the Covered Person in the research. At the time the research is initiated the activity is conducted or held by the Covered Person or Family Member within the prior 12 months is considered.

    a. Human Subjects Research. When a Covered Person has an FCOI that is Related to human subject research, MSK's primary objective must be to ensure that the FCOI does not impinge on

the welfare and rights of human subject research participants in the Related research. A Covered Person will generally be determined to have an FCOI relating to, and may not serve as the Principal Investigator or Co-Principal Investigator on, a human subject research protocol if the Covered Person has any of the following financial interests in any company sponsoring or otherwise supporting the research:

- **i.** Exceeds $25,000 in cash compensation over the prior 12-month period. This includes compensation from consulting services, speaking fees, honoraria, and any other non-equity interest provided for any other purpose;
- **ii.** Equity, including stock options or warrants, in a publicly-traded company that exceeds $25,000 in value as determined by current market value. Until such time as the ownership interest is divested, it is the responsibility of the Covered Person to notify the Compliance Department of a material change in the equity valuation;
- **iii.** Equity of any amount, including stock options or warrants, in a privately-held company that sponsors, funds, or otherwise supports Related Human Subjects Research;
- **iv.** Executive or Managerial Roles in a for-profit entity that sponsors, funds, or otherwise supports Related research in which the Covered Person is directly involved;
- **v.** The Covered Person is listed as an inventor of intellectual property being evaluated in the research and may receive licensing or royalty fees for the commercialization of the IP.

The COIAC or the Designated Officials may consider compelling considerations that may require the Covered Person to serve as PI or Co-PI in the Related human subjects research. The COIAC or Designated Officials will also review the extent to which the Covered Person may participate in the research activities, including, but not limited to:

- **i.** Subject recruitment;
- **ii.** Subject selection including prescreening for trial eligibility criteria;
- **iii.** Obtaining informed consent;
- **iv.** Clinical treatment of subjects;
- **v.** Performing the research interventions or procedures;
- **vi.** Adverse event evaluation and reporting

Compelling considerations may include a determination by the IRB that the risk to subjects participating in the Related research is “no more than minimal.” That a study is a Multicenter, Phase II and Phase III clinical trial with independent data monitoring may also be considered a compelling consideration, should the COIAC determine that the additional oversight is sufficient to minimize potential bias or the appearance of such.

b. Pre-Clinical Research. The Principal Investigator and any Key Personnel on a pre-clinical research study may not hold the following FI in the study’s sponsor unless a COI management plan has been implemented to manage the conflict(s) of interest:

- **i.** Exceeds $25,000 in cash compensation over the prior 12-month period. This includes compensation from consulting services, speaking fees, honoraria, and any other non-equity interest provided for any other purpose;
- **ii.** Equity, including stock options or warrants, in a publicly-traded company that exceeds

$25,000 in value as determined by current market value. Until such time as the ownership interest is divested, it is the responsibility of the Covered Person to notify the Compliance Department of a material change in the equity valuation;

iii. Equity of any amount, including stock options or warrants, in a privately-held company that sponsors, funds, or otherwise supports pre-clinical research;

iv. Executive or Managerial Roles in a for-profit entity that sponsors, funds, or otherwise supports Related research in which the Covered Person is directly involved;

v. The Covered Person is listed as an inventor of intellectual property being evaluated in the research and may receive licensing or royalty fees for the commercialization of the IP.

2. **Purchasing Decisions**. When a Covered Person's job duties include Purchasing Decisions and the Covered Person or his/her Family Member has an SFI that is determined to be Related to these Purchasing Decisions, the COIAC or Designated Officials will determine whether an FCOI exists; i.e., whether the SFI could directly and significantly affect these Purchasing Decisions. To make this determination, the COIAC or Designated Officials will consider all relevant facts, including but not limited to: the role of the Covered Person in the decision-making process; the relationship between the SFI and the potential Purchasing Decisions; and the availability of other qualified persons to make such Purchasing Decisions.

3. **Supervisory Duties.** When a Covered Person and/or his or her Family Member has an SFI that is determined to be Related to the Covered Person's supervision of post-doctorates, fellows, or other trainees, the COIAC or Designated Officials will determine whether an FCOI exists; i.e., whether the SFI could directly and significantly affect the Covered Person's supervision of the trainee.

C. Management Plans. If the COIAC or Designated Officials determine that an FCOI exists, a management plan will be developed and implemented. Management Plans must be implemented prior to the initiation of the activity for which the conflict exists. Covered Persons subject to a Management Plan must acknowledge and agree in writing to the terms of the Management Plan. Below are sample terms that a Management Plan may be composed of. This is a non-exhaustive list and alternative or additional terms may be included at the recommendation of the COIAC to address the individual FCOI under review :

1. Recusal or limitation of role for participation in research sponsored, funded, or otherwise supported by the entity with which the Covered person has an FCOI;
2. Ineligibility to serve as the Principal Investigator or Co-Principal Investigator on human subjects research sponsored, funded, or otherwise supported by the entity with which the Covered person has an FCOI;
3. Any limitations on serving as the treating physician on related single patient use treatment plans;
4. Recusal from data collection or analysis in research sponsored, funded, or otherwise supported by the entity with which the Covered person has an FCOI;
5. Oversight of research by a neutral internal or external third party;
6. Disclosure of the Financial Interest to research participants, relevant MSK staff members, laboratory members and staff, and the public.

The Compliance Department will provide the IRB with final draft copies of all management plans for FCOI related to human subjects research. The IRB will have the final authority to determine whether the FCOI is sufficiently managed to allow the research to be approved. The IRB will notify the Compliance Department

of its determination. The final approved copy of the plan will be sent to the Covered Person for signature. The Compliance Department maintains records of all signed Management Plans.

D. Transparency Standard. When a Covered Person has an FI that is determined to be Related to research, Purchasing Decisions, or supervision of trainees, but the FI is determined not to be an FCOI, MSK requires that the FI nevertheless be disclosed under the following circumstances:

1. **Research.** If the Covered Person who holds the FI has a role in the design, conduct, or reporting of research, disclosure will be made in the informed consent in human subject research, to staff working on research projects, and in any presentations relating to the research.
2. **Purchasing Decisions.** If the Covered Person who holds the FI has a role in Purchasing Decisions, disclosure will be made to other staff involved in the Purchasing Decisions.
3. **Supervision of Trainees.** If the Covered Person who holds the FI is responsible for mentoring trainees, disclosure of the FI will be made to the trainees.

E. Reporting of Financial Conflict of Interest and Management Plans 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**.** FCOI reports include the following: grant/contract number; project director/principal Investigator; name of the Investigator with the FCOI; name of the entity with which the Investigator has an FCOI; nature of FCOI; value (in ranges); description of how the FCOI relates to the research; basis for determining it is an FCOI; and key elements of MSK's Management Plan. The report will be submitted prior to MSK's expenditure of any funds under a PHS-funded research project. For any FCOI identified subsequent to the initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an investigator new to the project), MSK shall provide an FCOI report to the PHS Agency within 60 days and implement a management plan for that FCOI.

F. Annual FCOI Report to PHS Agencies. An annual report is required for any previously reported FCOI for the duration of the NIH-funded research project or until the FCOI ceases to exit. The annual reporting must be done at the same time as when the grantee is required to submit to the NIH the annual progress report, multi-year progress report, if applicable, or at time of extension.

G. Public Accessibility of FCOI Reports for PHS-Funded Research. MSK is required to ensure public accessibility of information concerning FCOIs identified for Senior/Key Personnel involved in PHS-funded research The information should include at a minimum: the investigator's name; the investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest and approximate dollar value (dollar ranges are permissible), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value. MSK will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of MSK's identification of a new FCOI.

Requests for information must be made in writing to MSK's Compliance Officer at the address below. The Compliance Department will respond to such request within five business days of receipt by the Department.

Direct written requests for publicly accessible FCOI reports to:

Chief Compliance Officer
Memorial Sloan-Kettering Cancer Center

1275 York Avenue
Box 705
New York, NY 10065

H. **Retrospective reviews** are undertaken in situations in which MSK identifies an FI that was not disclosed in a timely fashion by an Investigator working on PHS-funded research or, for whatever reason, was not previously reviewed by MSK during an ongoing PHS-funded research project. In these situations, MSK is required to review the FI to determine if it is Related to PHS-funded research and, if so, to determine whether an FCOI exists. If an FCOI exists and it was not identified or managed, MSK must:

1. Implement an interim Management Plan;
2. Within 120 days of detecting the FCOI, complete a retrospective review of the Investigator's activities and the PHS-funded research to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research;
3. Document the retrospective review, including, but not necessarily limited to: the project number, project title, the principal investigator or contact principal investigator (if multiple), name of the Investigator with the FCOI, name of the entity with which the FI exists, reason for the retrospective review, detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed), findings of the review, and conclusions of the review;
4. Based on the results of this retrospective review, if appropriate, update any previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, MSK is required to notify the PHS Awarding Component promptly and submit a mitigation report to it, in accordance with the PHS regulations.

   Retrospective reviews may also be undertaken in situations involving FIs that were not disclosed in a timely manner by a Covered Person working on non-PHS-funded research, or in situations involving FIs that were not disclosed that relate to a Covered Person's authority to make or influence Purchasing Decisions or supervisory duties.

VI. RESPONSIBILITIES OF MSK

MSK is responsible for maintaining procedures to implement and enforce this Policy, including:

A. Maintaining a Policy on Conflict of Interest that conforms with federal and state law and posting the Policy on MSK's website;

B. Taking reasonable steps to ensure that any sub recipient (e.g., subcontractors or consortium members) complies with the revised PHS Rule by incorporating as part of a written agreement with the sub recipient minimum contract terms set forth in Appendix II to this Policy

C. Maintaining a mechanism for Disclosure of FIs, including Travel, and identification of Covered Persons for whom Disclosure is required;

D. Maintaining records of Covered Person Disclosures and documentation on decisions regarding relatedness and on determinations as to whether an FCOI exists;

E. Documenting and enforcing Management Plans, as needed;

F. Monitoring compliance with Management Plans in accordance with the regulations on an ongoing basis until the completion of the PHS-funded research project;

G. Providing mandatory training on conflict of interest concepts and procedures;

H. Identifying situations in which retrospective reviews are required and assuring that such reviews are conducted and documented;

I. Providing FCOI reports to federal funding agencies and the public, as required by law.

VII. ENFORCEMENT

Covered Persons who fail to disclose a FI or Conflict of Commitment as required by this Policy, who fail to comply with a Management Plan established by the COIAC or Designated Officials, or who otherwise do not comply with this Policy may be subject to disciplinary action, up to and including termination of employment. The mere existence of a FI or FCOI, however, shall not subject a Covered Person to such sanctions.

If HHS determines that a PHS research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a FCOI that was not managed or reported as required, the investigator will disclose the FCOI in each public presentation of the results of the research and request an addendum to previously published presentations.

VIII. POLICY ON CONFLICT OF COMMITMENT

This policy is based on the premise that MSK employees' primary professional obligations are to MSK. While employees are allowed to engage in outside activities related to their MSK Institutional Responsibilities, those activities should not impinge on the employee's ability to perform his or her professional duties. Conflicts of Commitment generally develop when an employee's outside activities impose excessive demands on their time and effort, or when an employee enters into a fiduciary relationship with an outside entity. Activities that conflict with the principles laid out in the MSK Code of Conduct may also give rise to conflicts of commitment.

A. The policy in this section only applies to Covered Persons who are MSK employees.

B. **Disclosure**. Outside activities related to an employee's Institutional Responsibilities should be disclosed as set forth in Section IV of this Policy.

C. **Review.** The Compliance Department reviews all Disclosures in accordance with Section V of this Policy. Conflicts of Commitment may exist in the following circumstances:

1. **Time and Effort Commitments.** Covered Persons who engage in outside activities, regardless of whether they receive compensation for those activities, must have prior approval from their Division Head, Department or Program Chair, Service Chief, or immediate supervisor, as appropriate. Requests should be reviewed to determine whether the time and effort requirements of the activity could compromise the Covered Person's ability to fulfill his or her Institutional Responsibilities.

    i. Division Heads, Department or Program Chairs, Service Chiefs, and other supervisors should refer to MSK Business Conduct Guidelines in determining whether an employee's outside activities may create a conflict of commitment.

ii. The Compliance Department and the COIAC may review and make determinations in cases where time and effort commitments of any particular activity are exceptional. These determinations will be made in coordination with the Covered Person's department leadership.

2. **Executive or Managerial Roles.** Covered Persons must obtain prior approval from their immediate supervisor and the Compliance Department before accepting a role with fiduciary duties with an outside entity. The Compliance Department will work with the COIAC or COIAC Chair to determine whether a Management Plan is necessary for the role.

3. **Code of Conduct.** The MSK Code of Conduct lays out the standards of ethics and integrity MSK employees agree to follow in order to maintain MSK's role in the prevention, treatment, and ultimate goal of curing cancer. Outside activities, whether compensated or uncompensated, that conflict with the Code of Conduct are considered to be a conflict of commitment.

IX. GUIDELINES FOR OUTSIDE ACTIVITIES

A. Obligation of Employees to Maintain Confidentiality. In general, confidential information and material non-public information should not be shared with anyone except under specific circumstances. Special caution regarding disclosure of confidential information is warranted when consulting with industry or investment firms. If an employee has questions about whether to share such information, he/she should contact the Compliance Department or the Office of General Counsel.

When consulting with an outside entity, employees should keep the following general rules in mind.

1. Certain information is confidential and cannot lawfully be shared with outsiders.
2. As a general rule, information that is already in the public domain may be shared; certain information that is not public must not be disclosed to outsiders, particularly when that information may be used to trade in securities or when that information is covered under a duly executed Confidentiality Agreement with a third party.
3. Examples of information that must <u>always</u> be kept confidential include:
   - MSK's vendor pricing and contract terms.
   - MSK's strategic or business plans.
   - Outcome data and information related to unpublished research by others, or information that may be the subject of possible or pending patent applications. Patent issuance may be jeopardized by premature disclosure.
   - Patient-identified data unless the outside entity is authorized to receive it.

B. Investment Firms. In consulting for the investor community, it is often very difficult to avoid inadvertently sharing information that is confidential or not in the public domain. Sharing non-public information may lead to violation of federal securities laws, including laws prohibiting insider trading.

1. Insider trading sanctions may apply whether or not the person disclosing material non-public information realizes a financial gain.

2. Tipping and trading on the basis of material non-public information is a felony. Because even inadvertent breaches can lead to civil and criminal prosecution, employees must exercise extreme caution when engaging in discussions with the investment community. Employees should consider carefully whether the benefits of such consultation are worth the risks.

C. Obtain Personal Legal Advice. Agreements for consulting or advisory board membership are reviewed by MSK to ensure compliance with Center policies, but MSK is not party to the agreement. Employees who engage in work with outside organizations should consider retaining private legal counsel to ensure that their personal interests are protected.

D. Authorship Guidelines. Talks and papers that arise out of consulting and collaboration with industry must comply with MSK's Authorship Guidelines.

E. Use of MSK's name or resources by another party requires prior approval from the Department of Public Affairs.

F. Legal Actions. As set forth in the Rules and Regulations of the Medical Staff Policy 528, participating in outside legal actions requires prior approval from the Office of General Counsel. This includes malpractice cases or other lawsuits to which MSK is not a party where an employee is asked to provide expert testimony.

G. Participation in Industry Sponsored Presentations. Staff members may not make educational presentations or participate in scientific publications that are controlled by industry or that contain substantial portions written by someone who is not identified as an author or who is not properly acknowledged (e.g., that are ghost written). These activities are prohibited even if the staff member is not paid for the work.

Appendix I -- Summary of Financial Conflict of Interest Prior Approval and Timely Disclosure Requirements

OUTSIDE ACTIVITY	Who?	You			Your Family Members
	Do What?	Seek Prior Approval	Disclose in a Timely Manner		Disclose in a Timely Manner
	To?	Compliance via eCOI	Compliance via eCOI	Institutional Committees[2]	Compliance via eCOI
Compensation from a for-profit organization (including, for example: one-time consulting, serving on scientific advisory boards, giving a talk, consulting with investment firms, serving as expert or fact witness[1], reading slides or films for a lawsuit[1], serving on a DSMC)		YES	N/A	YES	YES[3]
Compensation received from a US government agency		NO	NO	NO	NO
Compensation received from foreign institutions or governments of other countries		N/A	YES	YES	YES[3]
Compensation received from a not-for-profit organization excluding 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.		N/A	YES	YES	YES[3]
Equity Interests including stock, stock options, and other ownership interests in publicly traded and non-publicly traded entities during the 12 months preceding the Disclosure, regardless of value. This excludes stock held in investment vehicles in which the Covered Person does not directly control investment decisions, such as mutual funds or retirement accounts.		YES	N/A	YES	YES[3]
Intellectual Property Rights and Interests upon receipt of income or if the IP is the subject of human subject research that involves the Covered Person.		NO	YES	YES	YES

[1] Approval by Office of General Counsel required.

[2] As may be required by such committees.

[3] For Family Members: With regard to any publicly traded entity, Disclosure is required if the value of any remuneration received from the entity in the 12 months preceding the Disclosure and the value of any Equity Interest in the entity as of the date of Disclosure, when aggregated, exceeds $5,000. With regard to any non-publicly traded entity, Disclosure is required if the value of any remuneration received from the entity in the 12 months preceding the Disclosure, when aggregated, exceeds $5,000 or when the Family Member holds any Equity Interest in the entity.

Appendix II – Minimum Contract Terms for Sub recipient Agreements

Written agreements with PHS grant sub recipients should establish whether the financial conflicts of interest policy of Institution or that of the sub recipient will apply to the sub recipient's Investigators, in accordance with the following procedures:

(i) If the sub recipient's Investigators must comply with the sub recipient's financial conflicts of interest policy, the sub recipient shall certify as part of the agreement referenced above that its policy complies with 42 CFR 50.604. In the alternative, the agreement shall state that sub recipient Investigators are subject to the financial conflicts of interest policy of Institution;

(ii) Additionally, if the sub recipient's Investigators must comply with the sub recipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the sub recipient to report all identified financial conflicts of interest to Institution. Such time period(s) shall be sufficient to enable Institution to provide timely FCOI reports, as necessary, to the PHS as required;

(iii) Alternatively, if the sub recipient's Investigators must comply with Institution's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the sub recipient to submit all Investigator disclosures of significant financial interests to Institution. Such time period(s) shall be sufficient to enable Institution to comply timely with its review, management, and reporting obligations.