
NYU LANGONE MEDICAL CENTER

**POLICIES ON
CONFLICTS OF INTEREST,
COMMITMENT
AND
CONSULTING**

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(Issued: April 1, 2009)

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NYU LANGONE MEDICAL CENTER
NYU HOSPITALS CENTER
NYU SCHOOL OF MEDICINE

POLICIES ON CONFLICTS OF INTEREST, COMMITMENT AND CONSULTING

ISSUED: April 1, 2009

PURPOSE AND SCOPE

In order to attain its vision of a world-class patient-centered integrated academic medical center, NYU Langone Medical Center must conduct its mission of quality-oriented and efficient patient care, the education of the next generation of physicians, and cutting-edge, translational research with the highest standard of intellectual objectivity and ethics. Fulfillment of this mission requires sponsored research, consulting and other activities that may give rise to interests which appear inconsistent with that mission. We must maintain a principled partnership with industry and avoid even the appearance of a conflict of interest.

These *Policies* set forth the Medical Center's policies and procedures on conflicts matters. These *Policies* provide a comprehensive system of identification, disclosure and oversight of all conflicts arising from the Medical Center's external interests and activities and the conduct of its business. They identify the types of personal activities and interests that require disclosure, provide a mechanism for how they will be evaluated, and present a framework for managing or eliminating conflicts should they arise. Most importantly, these *Policies* help identify situations where a conflict might arise. They are consistent with the policies of New York University, the Medical Center's Code of Conduct, all applicable laws and regulations, and, to the extent appropriate for our community, the latest best practices recommendations of the Association of American Medical Colleges.

These *Policies* apply to all of us – trustees, officers, faculty, staff, employees, trainees, students and volunteers - in the Medical Center community. For ease of reference, these *Policies* are organized in three parts.

Part I, *Business Conflicts of Interest*, sets forth conflicts of interest policies and principles for the entire Medical Center community. It consists of two policies: the *Policy on Conflicts of Interest in Business Affairs* and the *Policy on Trustee Conflicts of Interest*.

Part II, *Research Conflicts of Interest*, covers conflicts of interest in research and sponsored programs. It consists of two policies: the *Policy on Conflicts of Interest in Research and Sponsored Programs* and the *Policy on Institutional Conflicts of Interest in Human Subjects Research*.

Part III, *Conflicts of Commitment and Consulting*, covers conflicts arising from faculty members who engage in external activities. It consists of two policies: the *Policy on Faculty Conflicts of Commitment* and the *Policy on Faculty Consulting*.

While comprehensive, the *Policies* cannot cover every situation that may constitute a conflict. Please consult the FAQs on the webpage of the Conflicts Management Unit (a Division of the Office of Compliance) at <http://cmu.med.nyu.edu/> for additional guidance. When neither these *Policies* nor the FAQs address your concern, please contact the Conflicts Management Unit at 212-404-4079.

PART ONE

BUSINESS CONFLICTS OF INTEREST

Part One consists of two policies: the *Policy on Conflicts of Interest in Business Affairs* and the *Policy on Trustee Conflicts of Interest*. Together, these policies replace the Medical Center’s *Conflict of Interest Policy* dated March 18, 2004. All individuals in the Medical Center community are subject to the policies in Part One. The following table summarizes the application of these policies on different individuals in the Medical Center.

BUSINESS CONFLICTS OF INTEREST SUMMARY TABLE			
<u>Role and Responsibility</u>	<u>Disclosure</u>	<u>Review and Evaluation of Potential Conflicts</u>	<u>Review Policy & Criteria</u>
<ul style="list-style-type: none"> • Faculty/Investigators • Chairs/Vice Chairs • Vice Presidents/Asst. Deans/Assoc. Deans • Directors/Dept. Administrators • Oversight Committee Members • Persons with Purchasing Authority 	<ul style="list-style-type: none"> • Upon appointment • Annually • Upon request • Specific matters as they arise 	<p><i>Initial Review:</i> Office of Compliance</p> <p><i>Final Review:</i> Business Conflict of Interest Committee</p>	<p>The Medical Center will not engage in a matter giving rise to a conflict of interest involving an individual, except under a finding of extraordinary circumstances with a conflict management plan.</p>
<ul style="list-style-type: none"> • Other Employees • Residents/Trainees • Students • Volunteers 	<ul style="list-style-type: none"> • Upon request • Specific matters as they arise 	<p><i>Initial Review:</i> Office of Compliance</p> <p><i>Final Review:</i> Business Conflict of Interest Committee</p>	<p>The Medical Center will not engage in a matter giving rise to a conflict of interest involving an individual, except under a finding of extraordinary circumstances with a conflict management plan.</p>
<ul style="list-style-type: none"> • Corporate Officers (i.e., the Dean/CEO and the Senior Vice Presidents and Vice Deans) 	<ul style="list-style-type: none"> • Upon appointment • Annually • Upon request • Specific matters as they arise 	<p><i>Initial Review:</i> Office of Compliance</p> <p><i>Final Review:</i> Audit & Compliance Committee of the Board of Trustees</p>	<p>The Medical Center will not engage in a matter giving rise to a conflict of interest involving a Corporate Officer, except under a finding of extraordinary circumstances with a conflict management plan.</p>
<ul style="list-style-type: none"> • Trustees 	<ul style="list-style-type: none"> • Upon appointment • Upon reappointment • Upon request • Specific matters as they arise 	<p><i>Initial Review:</i> Office of Compliance</p> <p><i>Final Review:</i> Audit & Compliance Committee of the Board of Trustees</p>	<p>The Medical Center will not engage in a matter giving rise to a conflict of interest involving a Trustee, except under a finding of extraordinary circumstances with a conflict management plan.</p>

NYU LANGONE MEDICAL CENTER

POLICY ON CONFLICTS OF INTEREST IN BUSINESS AFFAIRS

Issue Date: April 1, 2009

Contents:

- I. Applicability
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 - III. Disclosure
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 - V. Recusal
 - VI. Definitions
 - VII. Examples of Conflicts of Interest
 - VIII. Enforcement
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 - X. Relationship to Other Policies
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I. Applicability

This Policy applies to all members of the Medical Center community -- employees, faculty, staff, residents, trainees, students, volunteers, and officers (each, an “NYULMC Member”) -- except trustees, who are governed by the *Policy on Trustee Conflicts of Interest*. All capitalized terms shall have the meaning set forth in Section VI below.

II. General Policy

A. NYULMC Members have a primary obligation to serve the purposes to which the Medical Center is dedicated. As part of this obligation, each NYULMC Member has a duty to conduct his or her Medical Center duties and the affairs of the Medical Center in a manner that promotes the best interests of the organization.

B. A “**Conflict of Interest**” exists when an NYULMC Member’s personal interests or activities within or outside of the Medical Center influence or appear to influence an NYULMC Member’s ability to promote objectively the best interests of the Medical Center. A Conflict of Interest may exist whenever an NYULMC Member participates, directly or indirectly, in the selection, award or administration of any business transaction which involves the Medical Center and the NYULMC Member, a member of his or her Immediate Family, or an entity in which he or she has a Financial Interest. Employment agreements between the Medical Center and the NYULMC Member are not business transactions giving rise to Conflicts of Interest under this Policy. Examples of Conflicts of Interest are set forth in Section VII below.

C. The Medical Center does not engage in any matter giving rise to a potential Conflict of Interest involving an NYULMC Member unless the matter has been fully disclosed and evaluated in accordance with this Policy and a plan for managing or eliminating the Conflict of Interest has been adopted.

III. Disclosure

A. Annual Disclosures. The following NYULMC Members must submit to the Office of Compliance annual disclosure forms upon appointment and annually thereafter:

- (i) Chairs, Vice-Chairs, Department Administrators, and all employees and officers at the level of Vice-President, Assistant Dean, Director or above;
- (ii) paid faculty members, whether full time or part time;
- (iii) investigators participating in the Medical Center's research or sponsored programs;
- (iv) persons engaged in purchasing decisions on behalf of the Medical Center; and
- (v) members of any Medical Center committees with supervision or oversight responsibilities over patient care, purchasing, research or education at the Medical Center (e.g., the Pharmacy and Therapeutic Committee (PNT) and the Institutional Review Board (IRB)).

The annual disclosure form will be provided to the NYULMC Member by the Office of Compliance and must be completed and returned within thirty (30) days of receipt. In addition, the Office of Compliance may request that any NYULMC Member complete an annual disclosure form at any time.

In the annual disclosure form, an NYULMC Member must, among other matters, certify compliance with the Medical Center's *Policies on Conflicts of Interest, Commitment and Consulting*, including this Policy, and disclose all entities in which he or she has a Financial Interest which he or she reasonably believes does or may do business with the Medical Center or competes or may compete with the Medical Center. Disclosures of Financial Interests must be made in specific amounts. In addition, as provided in the Medical Center's *Policy on Faculty Conflicts of Commitment*, faculty members must disclose all outside activities involving his or her professional competence. NYULMC Members may also be required to disclose additional personal interests, activities and relationships as mandated by regulatory requirements (e.g., IRS Form 990).

B. Specific Disclosures. All NYULMC Members must disclose to the Office of Compliance any specific situation that gives rise to a potential Conflict of Interest.

C. Confidentiality. Disclosures will be kept confidential and divulged by the Medical Center for review under the *Policies on Conflicts of Interest, Commitment and Consulting* on a need-to-know basis only.

IV. Review and Evaluation

A. Office of Compliance Initial Review. The Office of Compliance is responsible for reviewing disclosures and determining whether a potential Conflict of Interest exists under the circumstances. In cases involving an NYULMC Member other than a Corporate Officer where the Office of Compliance believes that a Conflict of Interest exists, the Office of Compliance will submit the matter to the Business Conflict of Interest Committee (BCOIC) for review in accordance with this Policy. In cases involving a Corporate Officer where the Office of Compliance believes that a Conflict of Interest exists, the Office of Compliance will submit the matter to the Audit and Compliance Committee.

B. Non-Corporate Officer Conflicts/BCOIC Review. The BCOIC is responsible for reviewing and evaluating each potential Conflict of Interest involving an NYULMC Member, other than a Corporate Officer, submitted to it by the Office of Compliance. As a matter of policy, if the BCOIC finds that a

Conflict of Interest exists, the Medical Center will not approve the matter unless the BCOIC determines, after reviewing all material facts, that extraordinary circumstances merit an exception and the BCOIC adopts a plan for managing and monitoring the Conflict of Interest which is fully consistent with the best interests of the Medical Center. The BCOIC must report to the Audit and Compliance Committee all findings it makes arising from its review and evaluation responsibilities under this Policy.

C. Corporate Officer Conflicts/Audit and Compliance Committee Review. The Audit and Compliance Committee is responsible for reviewing and evaluating each potential Conflict of Interest involving a Corporate Officer submitted to it by the Office of Compliance. As a matter of policy, if the Audit and Compliance Committee finds that a Conflict of Interest exists, the Medical Center will not approve the matter, unless the Audit and Compliance Committee determines, after reviewing all material facts, that extraordinary circumstances merit an exception and the Audit and Compliance Committee adopts a plan for managing and monitoring the Conflict of Interest which is fully consistent with the best interests of the Medical Center. The Audit and Compliance Committee must report to the Board of Trustees all findings it makes arising from its review and evaluation responsibilities under this Policy.

V. Recusal

No NYULMC Member shall participate, directly or indirectly, in the selection, award or administration of any matter that gives rise to a potential Conflict of Interest. In such event, the NYULMC Member must recuse himself or herself from the matter and notify the Office of Compliance as provided under Section III (B) above.

VI. Definitions

A. “**Conflict of Interest**” shall have the meaning ascribed to it in Section II (B) above.

B. “**Corporate Officer**” means the senior leadership of the Medical Center as defined from time to time by the Dean and CEO of the Medical Center.

C. A “**Financial Interest**” is held in an outside entity by an NYULMC Member when he or she or a member of his or her Immediate Family has a personal financial interest in the outside entity. Examples of Financial Interests are an Outside Position, Ownership Interests, Consulting Compensation or Royalty Income, where:

- (i) “**Outside Position**” means a position or appointment to serve, in either a personal or representative capacity, as a director, trustee, partner, senior executive, officer, or employee, whether paid or unpaid, at the outside entity;
- (ii) “**Ownership Interests**” are equity interests held, either directly or indirectly, including stock and stock options (or entitlement to the same); of any amount in either a publicly-traded or non-publicly-traded entity. (*Exception: Mutual Funds*– Interests of any amount in publicly-traded, diversified mutual funds are not Ownership Interests.);
- (iii) “**Consulting Compensation**” means consulting fees, honoraria, lecture fees, other emoluments, stock, stock options, royalties or “in kind” compensation directly or indirectly received from an entity (or entitlement to the same), whether for consulting, lecturing, or service on a scientific advisory board, data safety monitoring board, steering committee for a clinical trial, executive committee for a clinical trial, or other committee for an outside entity, or for any other purpose, that have been received in the past calendar year or are expected to be received in the next calendar year; and

- (iv) “**Royalty Income**” means royalty income (i.e., payments linked to product sales), or the written contractual right to receive future royalties, directly or indirectly under an issued or pending patent, license or copyright, that has been received in the past calendar year or is expected to be received in the next calendar year. For the purpose of this Policy, Royalty Income includes all income received by an NYULMC Member from NYU in accordance with the *NYU Statement of Policy on Intellectual Property*.

(*Exception: Salary from the Medical Center and cost-related payments for services or reimbursements from the Medical Center are not Financial Interests. Payments to the Medical Center, or via the Medical Center to the NYULMC Member, which are directly related to the reasonable costs incurred in the conduct of a research project or sponsored program or to the payment of indirect costs and are specified in a grant, agreement or contract between the Medical Center and a research sponsor are not Financial Interests.*)

D. “**Immediate Family**” means the person’s spouse, domestic partner, children, parents, siblings, equivalents by marriage, or other individuals residing in the person’s household.

E. An “**NYULMC Member**” means every member of the Medical Center community, including employees, faculty, staff, residents, trainees, students, volunteers and officers, except trustees.

VII. Examples of Conflicts of Interest

The following are situations that give rise to a Conflict of Interest and require disclosure to the Office of Compliance in accordance with this Policy. This list is by no means all-inclusive. In case of uncertainty as to whether or not a Conflict of Interest exists, an NYULMC Member should disclose the matter to the Office of Compliance. For example, some potential Conflicts of Interest occur when:

A. An NYULMC Member or a member of his or her Immediate Family has a Financial Interest in an entity or vendor that the Medical Center is contemplating doing business with (e.g., the Medical Center is contemplating purchasing, leasing or selling of goods, services, or real estate, or making or receiving a loan to or from such individual or entity, or is contemplating accepting a grant from such individual or entity for sponsored research).

B. An NYULMC Member or a member of his or her Immediate Family proposes that the Medical Center use or purchase goods in which the NYULMC Member has a proprietary interest (e.g., an NYULMC Member advocates the use of a device designed by the NYULMC Member).

C. An NYULMC Member, a member of his or her Immediate Family, or any entity in which he or she has a Financial Interest either engages in competition with a service provided by the Medical Center (e.g., by working for an organization which competes directly with the Medical Center, except that a member of the Medical Center’s medical staff who is also on the medical staff of another hospital does not constitute competition so long as the second appointment is not prohibited by his or her employment contract).

D. An NYULMC Member, a member of his or her Immediate Family, or any entity in which he or she has a Financial Interest recruits any Medical Center faculty member or employee or solicit business which knowingly disturbs, or could be expected to disturb, the existing professional or business relationships of the Medical Center with any faculty member, employee, health care provider or referral source.

E. An NYULMC Member proposes that the Medical Center hire or contract with a member of his or her Immediate Family for a position or activity that is within his or her direct or indirect supervision or

control. The employment of an NYULMC Member's Immediate Family with the Medical Center must be in accordance with NYU's *Policy on the Employment of Members of the Same Family*.

F. An NYULMC Member solicits or accepts a gift, favor or anything of monetary value from a contractor, vendor, patient, co-worker, volunteer or other person with whom the Medical Center has a business relationship, except as specifically provided in the Medical Center's *Policy on Acceptance and/or Solicitation of Gifts or Benefits From Vendors, Patients and Others*.

G. An NYULMC Member uses assets, property or labor of the Medical Center to his or her personal advantage.

H. An NYULMC Member discloses or uses any non-public information obtained in the course of discharging his or her duties and responsibilities at the Medical Center to his or her personal advantage.

VIII. **Enforcement**

A. Violations of this Policy are subject to disciplinary action, up to and including termination of employment or association with the Medical Center, in accordance with the Medical Center disciplinary policies and procedures applicable to the respective NYULMC Member.

B. Any failure to make a disclosure as required under this Policy by any members of a Medical Center committee will result in the member being suspended or removed from such committee.

IX. **Questions**

Any questions relating to this Policy should be directed to the Office of Legal Counsel or the Office of Compliance.

X. **Relationship to Other Policies**

A. This Policy and the *Policy on Trustee Conflicts of Interest* replace the Medical Center's *Conflict of Interest Policy* dated March 18, 2004.

B. This Policy is intended to supplement, but not replace, other policies and guidelines applicable to the NYULMC Member, including the conflict policies set forth in the NYU Faculty Handbook and elsewhere in the Medical Center's *Policies on Conflicts of Interest, Commitment and, Consulting*.

C. A matter involving an NYULMC Member's participation in research is reviewed under the Medical Center's *Policy on Conflicts of Interest in Research and Sponsored Programs* only.

NYU LANGONE MEDICAL CENTER

POLICY ON TRUSTEE CONFLICTS OF INTEREST

Issue Date: **Pending Approval**

Contents:

- I. Applicability
 - II. General Policy
 - III. Disclosure
 - IV. Review and Evaluation
 - V. Recusal
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I. Applicability

This Policy applies to trustees of the Medical Center (“Trustees”). All capitalized terms shall have the meaning set forth in Section VI below.

II. General Policy

A. Trustees have a primary obligation to serve the purposes to which the Medical Center is dedicated. As part of this obligation, each Trustee has a duty to conduct his or her Medical Center duties and the affairs of the Medical Center in a manner that promotes the best interests of the organization.

B. A “**Conflict of Interest**” exists when a Trustee’s personal interests or activities within or outside of the Medical Center influence or appear to influence a Trustee’s ability to promote objectively the best interests of the Medical Center. Any business transaction which involves the Medical Center and the Trustee, a member of his or her Immediate Family, or an entity in which he or she has a Material Interest gives rise to a Conflict of Interest. Examples of Conflicts of Interest are set forth in Section VII below.

C. The Medical Center does not enter into any business transactions with Trustees, members of their Immediate Family, or entities in which any Trustee has a Material Interest, and does not engage in any other matter which gives rise to a potential Conflict of Interest. An exception to this policy may be made only when the Audit and Compliance Committee of the Board of Trustees determines that extraordinary circumstances merit an exception as provided in Section IV (C) below.

III. Disclosure

A. Disclosure – General on Appointment and Re-Appointment. Trustees must submit a general disclosure statement upon appointment, upon each triennial reappointment thereafter, and upon request of the Office of Compliance. In the general disclosure statement, a Trustee must certify compliance with this Policy and disclose all entities in which he or she holds a Material Interest which he or she reasonably

believes does or may do business with the Medical Center or competes or may compete with the Medical Center. All disclosures must be made in specific amounts. The Trustee must disclose any entity in which the Trustee and/or any member of his or her Immediate Family:

- (i) has a director or trustee position;
- (ii) has an officer or senior executive position;
- (iii) is a partner; or
- (iv) owns or controls more than 5% of the entity's outstanding equity.

The general disclosure statement form will be provided to each Trustee by the Office of Compliance and must be completed and returned within thirty (30) days of receipt and prior to the first meeting of the Board of Trustees (or a Committee thereof) following his or her appointment or reappointment. Trustees may also be required to disclose additional personal interests, activities and relationships as mandated by regulatory requirements (e.g., IRS Form 990).

B. Disclosure – Specific Situations. Trustees must disclose to the Office of Compliance any specific situation that gives rise to a potential Conflict of Interest involving the Trustee.

C. Confidentiality. All disclosures will be kept confidential and divulged by the Medical Center solely for review under this Policy on a need-to-know basis.

IV. Review and Evaluation

A. Office of Compliance Initial Review. The Office of Compliance is responsible for reviewing each disclosure received from any Trustee and for determining whether a potential Conflict of Interest exists under the circumstances. In cases where the Office of Compliance believes that a Conflict of Interest exists, the Office of Compliance will submit the matter to the Audit and Compliance Committee for review in accordance with this Policy.

B. Audit and Compliance Committee Review. The Audit and Compliance Committee is responsible for reviewing and evaluating each potential Conflict of Interest involving a Trustee submitted by the Office of Compliance. As a matter of policy, if the Audit and Compliance Committee finds that a Conflict of Interest exists, the Medical Center will not approve the matter, unless the Audit and Compliance Committee determines, after reviewing all material facts, that extraordinary circumstances merit an exception and the Audit and Compliance Committee adopts a plan for managing and monitoring the Conflict of Interest which is fully consistent with the best interests of the Medical Center. The Audit and Compliance Committee must report to the Board of Trustees all findings it makes arising from its review and evaluation responsibilities under this Policy.

V. Recusal

No Trustee shall participate in the discussion and vote of any matter that gives rise to a potential Conflict of Interest. In such event, the Trustee must recuse himself or herself from participation in the discussion and vote of the matter and notify the Office of Compliance as provided under Section III(B) above.

VI. Definitions

A. **“Conflict of Interest”** shall have the meaning ascribed to it in Section II(B) above.

B. **“Immediate Family”** means the person's spouse, domestic partner, children, parents, siblings, equivalents by marriage, or other individuals residing in the person's household.

C. A “**Material Interest**” in an entity is held when a Trustee and/or a member of his or her Immediate Family (a) is a director, trustee, partner, officer or senior executive in the entity or (b) has a financial interest of any kind in the entity which, in view of all the circumstances, is substantial enough that it might affect, or reasonably be perceived to affect, the Trustee’s judgment with respect to transactions between the Medical Center and the entity. A “financial interest” includes all forms of direct and indirect compensation, remuneration, ownership or control of the entity.

VII. Examples of Conflicts of Interest

The following are situations that give rise to a Conflict of Interest and require disclosure to the Office of Compliance in accordance with this Policy. This list is by no means all-inclusive. In case of uncertainty as to whether or not a Conflict of Interest exists, a Trustee should disclose the matter to the Office of Compliance. Some potential Conflicts of Interest occur when:

A. A Trustee or a member of his or her Immediate Family has a Material Interest in an entity or vendor that the Medical Center is contemplating doing business with (e.g., the Medical Center is contemplating purchasing or selling of goods, services, or real estate, or making or receiving a loan to or from such individual or entity, or is contemplating accepting a grant from such individual or entity for sponsored research).

B. A Trustee or a member of his or her Immediate Family proposes that the Medical Center use or purchase goods in which the Trustee has a proprietary interest (e.g., a Trustee advocates the use of a device designed by a member of the Trustee’s Immediate Family).

C. A Trustee, a member of his or her Immediate Family, or any entity in which he or she has a Material Interest either engages in competition with a service the Medical Center offers (e.g., by working for an organization which competes directly with the Medical Center).

D. A Trustee, a member of his or her Immediate Family, or any entity in which he or she has a Material Interest recruits any Medical Center faculty member or employee or solicits business which knowingly disturbs, or could be expected to disturb, the existing professional or business relationships of the Medical Center with any faculty member, employee, health care provider or referral source.

E. A Trustee proposes that the Medical Center hire or contract with a member of his or her Immediate Family for a position or activity that is within the Board of Trustees’ direct supervision or control. The employment of a Trustee’s Immediate Family with the Medical Center must be in accordance with NYU’s *Policy on the Employment of Members of the Same Family*.

F. A Trustee solicits or accepts a gift, favor or anything of monetary value from a contractor, vendor, patient, co-worker, volunteer or other person with whom the Medical Center has a business relationship, except as specifically provided in the Medical Center’s *Policy on Acceptance and/or Solicitation of Gifts or Benefits From Vendors, Patients and Others*.

G. A Trustee uses any assets, property or labor of the Medical Center to his or her personal advantage.

H. A Trustee discloses or uses any non-public information obtained in the course of discharging his or her duties and responsibilities at the Medical Center to his or her personal advantage.

VIII. **Enforcement**

Violations of this Policy are subject to corrective action up to and including termination of association with the Medical Center in accordance with the policies and procedures applicable to Trustees.

IX. **Questions**

Any questions relating to this Policy should be directed to the Office of Legal Counsel or the Office of Compliance.

X. **Restatement**

This Policy and the Medical Center's *Policy on Conflicts of Interest in Business Affairs* replace the Medical Center's *Conflict of Interest Policy* dated March 18, 2004.

PART TWO

RESEARCH CONFLICTS OF INTEREST

Part Two consists of two policies: the *Policy on Conflicts of Interest in Research and Sponsored Programs* and the *Policy on Institutional Conflicts of Interest in Human Subjects Research*. The *Policy on Conflicts of Interest in Research and Sponsored Programs* replaces the *Investigator Financial Interest Disclosure and Conflict of Interest Policy* dated October 1, 1995.

The Medical Center has a strong commitment to the principle of open and objective inquiry in the conduct of its research. Investigators participating in research at the Medical Center have a primary obligation to conduct the research free of the appearance of conflict. To participate in research that might be perceived to be tainted due to a personal or institutional interest is contrary to this commitment unless the conflict of interest is managed or eliminated. Under certain circumstances, an investigator's personal interest (or the Medical Center's institutional interest) might be too significant to permit participation in the research. The following table summarizes these policies:

Role/Activity	Disclosure	Review and Evaluation	Review Policy & Criteria
<p>All Investigators participating in Research or applying for a Sponsored Program, including</p> <ul style="list-style-type: none"> • Investigators • Program Directors • Key Personnel (e.g., Study Coordinator, Outside Collaborator) 	<ul style="list-style-type: none"> • Annual disclosures, as required by Part One of these <i>Policies</i> • Protocol Disclosures: <ul style="list-style-type: none"> • With Initial Protocol Submission • Annual Continuations • Before Obtaining New Interest 	<p><i>Initial Review of Financial Interests:</i> Office of Compliance</p> <p><i>Initial Review of Significant Financial Interests:</i> Research Conflict of Interest Committee</p> <p><i>Appeals to:</i> Vice Dean for Science</p>	<p>The Medical Center will not permit an Investigator with a Significant Financial Interest project to participate in the project, except after a finding of Compelling Circumstances and the creation of a conflict management plan.</p>
<p>Any Human Subjects' Research (i) using a product covered by NYU intellectual property rights or (ii) sponsored by an entity in which NYU owns equity obtained via a licensing arrangement.</p>	<ul style="list-style-type: none"> • Specific matters must be reported as they arise by the OIL, OCT, SPA, IRB and any other party aware of a potential institutional conflict. 	<p><i>Initial Review:</i> Office of Compliance</p> <p><i>Final Review:</i> Research Conflict of Interest Committee</p> <p><i>Appeals to:</i> Vice Dean for Science</p>	<p>The Medical Center will not engage in a Human Subjects' Research project if it has an Institutional Financial Interest, except after a finding of Compelling Circumstances and the creation of a conflict management plan.</p>

NYU LANGONE MEDICAL CENTER

POLICY ON CONFLICTS OF INTEREST IN RESEARCH AND SPONSORED PROGRAMS

Issue Date: April 1, 2009

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- I. Applicability
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I. Applicability

This Policy applies to all Investigators participating in a Sponsored Project conducted at or under the auspices of the Medical Center. All capitalized terms shall have the meaning set forth in Section V below.

II. General Policy

A. Investigators participating in a Sponsored Project conducted at or under the auspices of the Medical Center have a primary obligation to serve the purposes to which the Medical Center is dedicated. As part of this obligation, Investigators have a duty to conduct research free of any appearance of impropriety or conflict of interest.

B. A “**Conflict of Interest**” exists in a Sponsored Project when an Investigator’s Financial Interest might reasonably appear to affect or be affected by the design, conduct or reporting of the Sponsored Project. All potential Conflicts of Interest require disclosure, evaluation and either management or elimination under this Policy.

C. A Conflict of Interest may exist whenever an Investigator has a Financial Interest in a Sponsored Project. When an Investigator has a Financial Interest that is not a Significant Financial Interest, the Investigator’s participation in the Sponsored Project will generally be permitted, subject to a conflict management plan issued by the Office of Compliance on behalf of the Research Conflict of Interest Committee (RCOIC).

D. Certain Conflicts of Interest are too significant to manage and must be eliminated. When an Investigator has a Significant Financial Interest, the Investigator may not participate in a Sponsored Project. An exception to this policy may be made only when the Senior Vice President and Vice Dean for Science of the Medical Center or the RCOIC determines that Compelling Circumstances exist to merit an exception and a conflict management plan is adopted to maintain research integrity and serve the best interests of subjects enrolled in the research.

III. Disclosure

Investigators must (i) submit an annual disclosure form upon request of the Office of Compliance and annually thereafter and (ii) submit an investigator financial interest disclosure form (a) upon submission of each proposal of a Sponsored Project, (b) at each annual continuation of such Sponsored Project thereafter, and (c) prior to obtaining any new Financial Interest in the Sponsored Project while such Sponsored Project remains on-going. Disclosures of Financial Interests must be made in specific amounts.

A. Annual Disclosures. All Investigators, except non-employee Investigators, are required under the Medical Center's *Policy on Conflicts of Interest in Business Affairs* to complete and return an annual disclosure form.

B. Proposal Disclosure – Upon Submission. Each Investigator planning to participate in a proposed Sponsored Project must submit an investigator financial interest disclosure form at the time of submission of the Sponsored Project to the IRB, to the IACUC and/or to a Sponsored Research Office, as applicable. On the disclosure form, Investigators must disclose all Financial Interests in the Sponsored Project. An Investigator must submit the disclosure form even if the Investigator is not disclosing a Financial Interest in the Sponsored Project.

C. Proposal Disclosure – Upon Annual Continuations. Each Investigator participating in a Sponsored Project must also submit a new disclosure form at each annual continuation of the Sponsored Project.

D. Proposal Disclosure – New Financial Interests. While a Sponsored Project is on-going, an Investigator must disclose on a new disclosure form any new Financial Interest prior to acquiring such Financial Interest. The Investigator must not acquire the new Financial Interest unless and until the acquisition has been disclosed, reviewed, evaluated and permitted as contemplated by this Policy.

E. Confidentiality. All disclosures will be kept confidential and disclosed only on a need-to-know basis as required to perform the review and evaluation required by this Policy and the Medical Center's *Policies on Conflicts of Interest, Commitment and Consulting*.

IV. Review and Evaluation

A. Office of Compliance Review. The Office of Compliance is responsible for reviewing each disclosure of a Financial Interest held by an Investigator in a Sponsored Project and for organizing such disclosures into the following four categories: (i) disclosures where no Financial Interest is disclosed, (ii) initial disclosures for the Sponsored Project of a Financial Interest which is not a Significant Financial Interest, (iii) initial disclosures for the Sponsored Project of a Significant Financial Interest, and (iv) disclosures of a Financial Interest for the Sponsored Project that has previously been reviewed, evaluated, and made subject to a conflict management plan issued under this Policy.

- (i) For disclosures where no Financial Interest is disclosed, the Office of Compliance shall advise the Investigator and the appropriate Research Administration Office.
- (ii) For initial disclosures for the Sponsored Project of a Financial Interest, the Investigator's participation will generally be permitted, subject to an appropriate conflict management plan issued by the Office of Compliance on behalf of the RCOIC. Conflict management plans issued by the Office of Compliance may be appealed to the RCOIC.

Notwithstanding the foregoing, if the Office of Compliance believes that the disclosure gives rise to a significant Conflict of Interest, the Office of Compliance may submit the matter to the RCOIC for its review and evaluation.

- (iii) For initial disclosures for the Sponsored Project of a Significant Financial Interest, the Office of Compliance will submit the matter to the RCOIC for its review and evaluation. Conflict management plans issued by the RCOIC may be appealed to the Medical Center's Senior Vice President and Vice Dean for Science.
- (iv) For disclosures of a Financial Interest for a Sponsored Project which has previously been reviewed and evaluated and is subject to a conflict management plan issued under this Policy, the Office of Compliance may, in its discretion, approve the continuation of the conflict management plan without referral to the RCOIC if both (a) the principal investigator and the Investigator with the Financial Interest, if a different individual, certify that he or she and the Sponsored Project have adhered to all requirements of the conflict management plan and (b) the nature and amount of the Financial Interest has not changed or materially increased since the issuance of the conflict management plan. If the nature or amount of the previously reviewed Financial Interest has changed or materially increased, the disclosed Financial Interest shall be reviewed and evaluated under this Policy as an initial disclosure for the Sponsored Project of a Financial Interest as provided in (ii) and (iii) above, a new conflict management plan may be adopted, and the Investigator's failure to disclose the change in the nature or amount of the previously reviewed Financial Interest will be treated as a violation of this Policy as provided in Section VII below.

B. RCOIC Review. The RCOIC is responsible for reviewing and evaluating each matter submitted to it by the Office of Compliance. The RCOIC shall make a determination on whether Compelling Circumstances exist to justify the Investigator's participation in the Sponsored Project notwithstanding the disclosed Financial Interest and, if Compelling Circumstances are found, approve a conflict management plan as contemplated below.

C. Conflict Management Plan. If an Investigator's participation in a Sponsored Project is permitted notwithstanding his or her disclosed Financial Interest, the Investigator's participation must be subject to a conflict management plan which maintains research integrity and serves the best interests of subjects enrolled in the research. Possible management strategies to be considered are listed in the *Research Conflict of Interest Committee - Operating Guidelines* (Appendix B to the Medical Center's *Policies on Conflicts of Interest, Commitment and Consulting*). The conflict management plan must be agreed to by both the principal investigator on the Sponsored Project and the Investigator with the disclosed Financial Interest, if a different individual. All conflict management plans are to be considered as part of the IRB or the IACUC's review, as applicable.

D. Appeals to the Senior Vice President and Vice Dean for Science. Determinations of the RCOIC may be appealed to the Medical Center's Senior Vice President and Vice Dean for Science. Appeals must be in writing and submitted to the Office of Compliance. Appeals may be made by the Office of Compliance, the RCOIC, the Dean/CEO of the Medical Center, the Senior Vice President and Vice Dean for Science, the Department Chair, the Investigator with the Financial Interest, or any other Investigator on the Sponsored Project. The Office of Compliance will provide copies of the appeal to the Senior Vice President and Vice Dean for Science and the RCOIC Chair. Decisions of the Senior Vice President and Vice Dean for Science are final.

E. **Timing.** The review and evaluation of an Investigator's disclosure under this Policy must be completed prior to the expenditure of any awarded funds for the Sponsored Project or any commencement of the Sponsored Project (including any enrollment of research subjects).

V. **Definitions**

A. **"Compelling Circumstances"** means those facts that convince the Vice Dean for Science and the RCOIC that an Investigator may participate in a Sponsored Project despite the existence of a Significant Financial Interest. Factors that may be evaluated by the RCOIC in determining whether Compelling Circumstances are present are listed in the *Research Conflict of Interest Committee - Operating Guidelines* (Appendix B to the Medical Center's *Policies on Conflicts of Interest, Commitment and Consulting*).

B. **"Conflict of Interest"** shall have the meaning ascribed to it in Section II (B) above.

C. A **"Financial Interest"** is held in a Sponsored Project when an Investigator or a member of his or her Immediate Family (i) has a personal financial interest in the Research Sponsor or in any other Financially-Interested Company or (ii) has Intellectual Property Rights covering products or processes being used in the Sponsored Project. Examples of Financial Interests are an Outside Position, Ownership Interests, Consulting Compensation, Royalty Income and Intellectual Property Rights, where:

- (i) An **"Outside Position"** means a position or appointment to serve, in either a personal or representative capacity, as a director, trustee, partner, senior executive, officer, or employee, whether paid or unpaid, at any outside entity.
- (ii) **"Ownership Interests"** are equity interests held, either directly or indirectly, including stock and stock options (or entitlement to the same); of any amount in either a publicly-traded or non-publicly-traded entity. (*Exception: Mutual Funds*– Interests of any amount in publicly-traded, diversified mutual funds are not Ownership Interests.)
- (iii) **"Consulting Compensation"** means consulting fees, honoraria, lecture fees, other emoluments, stock, stock options, royalties or "in kind" compensation directly or indirectly received from an entity (or entitlement to the same), whether for consulting, lecturing, or service on a scientific advisory board, data safety monitoring board, steering committee for a clinical trial, executive committee for a clinical trial, or other committee for an outside entity, or for any other purpose, that have been received in the past calendar year or are expected to be received in the current or next calendar year.
- (iv) **"Royalty Income"** means royalty income (i.e., payments linked to product sales), or the written contractual right to receive future royalties, directly or indirectly, under an Intellectual Property Right that has been received in the past calendar year or is expected to be received in the current or next calendar year, and includes, for the purpose of this Policy, all income received by an Investigator from NYU in accordance with the *NYU Statement of Policy on Intellectual Property*.
- (v) An **"Intellectual Property Right"** is an issued or pending patent, license or copyright covering products or processes being used in the Sponsored Project and includes, for the purpose of this Policy, the right to income from NYU in connection with a patent, license or copyright held by or to be held by NYU (for further information, see *NYU Statement of Policy on Intellectual Property*).

(*Exception:* Salary from the Medical Center and cost-related payments for services or reimbursements from the Medical Center are not Financial Interests. Payments to the Medical Center, or via the Medical Center to the Investigator, which are directly related to the reasonable costs incurred in the conduct of research or to the payment of indirect costs and are specified in a grant, agreement or contract between the Medical Center and the Research Sponsor are not Financial Interests.)

D. “**Financially-Interested Company**” means an outside entity which would reasonably appear to affect or be affected by the conduct or outcome of the Sponsored Project at the Medical Center. This term includes: (1) the manufacturer or distributor (including business partners and affiliates) of any drug or device or other product or process being used in the Sponsored Project and (2) any entity acting as the agent of the Research Sponsor or another Financially-Interested Company (e.g., a contract research organization). The term also *may* include a company that provides *direct* and *primary* competition for the investigational product if the Investigator actually knows that the financial interests of the company would reasonably appear to affect or be affected by the Sponsored Project.

E. “**Human Subjects Research**” means a systematic investigation performed with human subjects (including development, testing, and evaluation) designed to develop or contribute to generalizable knowledge, regardless of the source of funding.

F. “**IACUC**” refers to the Medical Center’s Institutional Animal Care and Use Committee.

G. “**Immediate Family**” means the person’s spouse, domestic partner, children, parents, siblings, equivalents by marriage, or other individuals residing in the person’s household.

H. “**IRB**” refers to the Medical Center’s Institutional Review Board and any other authorized Institutional Review Board for Human Subjects Research conducted at or under the auspices of the Medical Center.

I. An “**Investigator**” is any person doing any of the following in connection with a Sponsored Project at or under the auspices of the Medical Center, whether conducted at an NYU-owned facility, at a Medical Center-owned facility, at the Bellevue Medical Center, at the Manhattan Harbor Veterans Administration Medical Center, at any other affiliated entity, or anywhere else in the world:

1. Designing, conducting or directing the Sponsored Project;
2. Applying, on behalf of the Medical Center, for grants or awards to perform the Sponsored Project;
3. Serving as the principal investigator/program director, co-investigator, or sub-investigator;
4. Enrolling subjects (including obtaining informed consent, if applicable) or making decisions related to eligibility for enrollment; or
5. Analyzing, reporting, presenting or publishing research data.

All key personnel, including the study coordinator, listed on a submission for the Sponsored Project to the IRB, the IACUC or the applicable Sponsored Research Office are Investigators.

J. “**Non-Human Subjects Research**” means basic research, animal research, and other research that is not Human Subjects Research, regardless of the source of funding.

K. “**Pre-Clinical Research**” means any Non-Human Subjects Research which is reasonably anticipated (1) to be a component of a submission to the FDA related to a product or process to be tested on human subjects (including an IND or IDE submission) or (2) to develop into research involving human subjects within the coming twelve (12) months.

L. A “**Research Sponsor**” is any government (federal, state, or municipal), foundation, not-for-profit or for-profit entity providing either monetary or material support for a Sponsored Project.

M. “**Significant Financial Interest**” is defined as follows:

- (i) For a Human Subjects Research project, a Financial Interest is a “**Significant Financial Interest**” if it is (a) any Outside Position (including as a director, trustee, partner, senior executive, officer or employee); (b) Ownership Interests (including stocks, options and warrants) of any amount; (c) Consulting Compensation (including consulting income and honoraria) of greater than \$10,000 in any relevant year; (d) Royalty Income of greater than \$10,000 in any relevant year; or (e) any Intellectual Property Right.
- (ii) For a Pre-Clinical Research project, a Financial Interest is a “**Significant Financial Interest**” if it is (a) any Outside Position (including as a director, trustee, partner, senior executive, officer or employee); (b) Ownership Interests (including stocks, options and warrants) of any amount; (c) Consulting Compensation (including consulting income and honoraria) of greater than \$10,000 in any relevant year; or (d) Royalty Income of greater than \$10,000 in any relevant year.
- (iii) For all Non-Human Subjects Research (other than Pre-Clinical Research) or Sponsored Programs, a Financial Interest is a “**Significant Financial Interest**” if it is (a) any Outside Position (including as a director, trustee, partner, senior executive, officer or employee); (b) Ownership Interests (including stocks, options and warrants) of greater than \$25,000 in a publicly-held company; (c) Ownership Interests (including stocks, options and warrants) of any amount in a privately-held company, (d) Consulting Compensation (including consulting income and honoraria) of greater than \$25,000 in any relevant year; or (e) Royalty Income of greater than \$25,000 in any relevant year.

N. “**Sponsored Program**” means any activity that receives funding from outside the Medical Center other than a Human Subjects Research project and a Non-Human Subjects Research project, including education and service activities. (*Exception: CME Activities*– Commercial support of any certified-CME-activity is not a Sponsored Program.)

O. “**Sponsored Project**” means any Human Subjects Research project, any Non-Human Subjects Research project, or any Sponsored Program.

P. “**Sponsored Research Office**” means the Medical Center office responsible for the Medical Center’s review and administration of a Sponsored Project proposal. The Sponsored Research Offices are the Office of Sponsored Programs Administration (SPA), the Office of Clinical Trials (OCT) and the Office of Industrial Liaison (OIL).

VI. Examples of Research Conflicts of Interest

Examples of matters arising under this Policy will be maintained and updated periodically on the Office of Compliance’s webpage at <http://cmu.med.nyu.edu/>.

VII. Enforcement

A. Violations of this Policy are subject to disciplinary action, up to and including termination of employment or association with the Medical Center, in accordance with the Medical Center disciplinary policies and procedures applicable to the respective Investigator.

B. A new proposal or continuation submission for a Sponsored Project will not be considered complete, and the Medical Center will not proceed with a Sponsored Project or submit a proposal to a Research Sponsor, unless all Investigators participating in the Sponsored Project have both (i) submitted an annual disclosure form as provided in the *Policy on Conflicts of Interest in Business Affairs* within the previous twelve (12) months and (ii) submitted an investigator financial interest disclosure form for the Sponsored Project as required by this Policy. Failure to make timely submissions will result in delays.

C. If there is a determination by the Senior Vice President and Vice Dean for Science that the failure of an Investigator to comply with this Policy has biased the design, conduct, or reporting of a Sponsored Project, the Medical Center shall promptly notify the Research Sponsor and any other potentially affected party.

VIII. Administration

A. Questions. Any questions relating to this Policy should be directed to the Office of Legal Counsel or the Office of Compliance.

B. Reporting. The RCOIC and the Office of Compliance must provide reports of its activities under this Policy to the Senior Vice President and Vice Dean for Science on an annual basis.

C. Records Retention. The Office of Compliance shall maintain records of all disclosures it receives, all determinations made, all management plans, all final decisions, and all other actions under this Policy for the longest of (i) three (3) years from the date of submission of final expenditure reports for the Sponsored Project, (ii) any other period required by the research agreement with the Research Sponsor, or (iii) until the resolution of any action involving those records.

IX. Relationship to Other Policies

A. This Policy replaces the *Investigator Financial Interest Disclosure and Conflict of Interest Policy* dated October 1, 1995

B. This Policy is intended to supplement, but not replace, other policies and guidelines applicable to the Investigator, including the conflict policies set forth in the NYU Faculty Handbook and elsewhere in the Medical Center's *Policies on Conflicts of Interest, Commitment and Consulting*.

NYU LANGONE MEDICAL CENTER

POLICY ON INSTITUTIONAL CONFLICTS OF INTEREST IN HUMAN SUBJECTS RESEARCH

Issue Date: April 1, 2009

Contents:

- I. Purpose, Scope and Policy
 - II. Reporting
 - III. Review and Evaluation
 - IV. Examples of Institutional Conflicts of Interest
 - V. Enforcement
 - VI. Administration
-

I. Purpose, Scope and Policy

A. An “**Institutional Conflict of Interest**” arises in human subjects’ research when a financial interest of New York University (NYU) or the Medical Center may affect or appear to affect the design, conduct, reporting, review, or oversight of the human subjects’ research. Institutional Conflicts of Interest are of significant concern when an Institutional Financial Interest (as defined below) creates the potential for inappropriate influence over a human subjects’ research project, particularly to the integrity of the research and the safety and care of patients enrolled in the research. All potential Institutional Conflicts of Interest in human subjects’ research require disclosure, evaluation and either management or elimination under this Policy.

B. An “**Institutional Financial Interest**” is held when either (i) NYU or the Medical Center receives or might reasonably be expected to receive royalty income from the sale of a product covered by any patent, license or copyright, whether issued or pending, held by NYU or the Medical Center and proposed to be used in the human subjects’ research project; and/or (ii) NYU or the Medical Center holds or proposes to hold, directly or indirectly, any equity interests of any amount (or entitlement to the same), in the research sponsor for the human subjects’ research project, whether such research sponsor is public or non-public, through NYU’s or the Medical Center’s technology licensing activities or investments related to such activities.

C. Certain Institutional Conflicts of Interest are too significant to manage and must be eliminated. As a matter of policy, the Medical Center will not participate in a human subjects’ research project when it has an Institutional Financial Interest. An exception to this policy may be made only when the Senior Vice President and Vice Dean for Science of the Medical Center or the Research Conflict of Interest Committee (RCOIC) determines that Compelling Circumstances (as defined below) exist to merit an exception and a conflict management plan is adopted to maintain research integrity and serve the best interests of subjects enrolled in the research.

D. Under this Policy, “**Compelling Circumstances**” means those facts that convince the Vice Dean for Science and the RCOIC that the Medical Center may participate in a human subjects’ research project despite the existence of an Institutional Financial Interest. Factors that may be evaluated by the RCOIC in determining whether Compelling Circumstances are present are listed in the *Research Conflict of*

Interest Committee - Operating Guidelines (Appendix B to the Medical Center's *Policies on Conflicts of Interest, Commitment and Consulting*).

II. **Reporting**

A. The Office of Industrial Liaison (OIL) shall periodically develop a list of Institutional Financial Interests, including (i) all drugs, devices and other possible investigational products covered by issued or pending patents, licenses or copyrights held by NYU or the Medical Center which may be the subject of human subjects' research at the Medical Center, and the entities that have licensed such drugs, devices and other investigational products, and (ii) the entities in which NYU or the Medical Center has acquired any equity interests (or entitlements to the same) of any amount through NYU's or the Medical Center's technology licensing activities.

B. The Office of Industrial Liaison shall periodically provide such lists to the Office of Clinical Trials (OCT), the Office of Sponsored Programs Administration (SPA), the School of Medicine's Institutional Review Board, and the Office of Compliance.

C. OIL, the OCT, SPA, and the Medical Center's IRB shall review all proposed human subjects' research projects against such lists to identify potential Institutional Conflicts of Interest and report identified matters to the Office of Compliance.

III. **Review and Evaluation**

A. Office of Compliance Review. The Office of Compliance is responsible for reviewing each disclosure of an Institutional Financial Interest in a human subjects' research project and for determining whether an Institutional Conflict of Interest exists under the circumstances. In cases where the Office of Compliance determines that an Institutional Conflict of Interest may exist, the Office of Compliance will submit the matter to the RCOIC.

B. RCOIC Review. The RCOIC is responsible for reviewing and evaluating each potential Institutional Conflict of Interest matter submitted to it by the Office of Compliance. The RCOIC shall make a determination on whether Compelling Circumstances exist to justify the Medical Center's participation in the project.

C. Conflict Management Plan. If the Medical Center's participation in a project is permitted notwithstanding the Institutional Financial Interest, the Medical Center's participation is subject to a conflict management plan which maintains research integrity and serves the best interests of subjects enrolled in the research. Management strategies to be considered are listed in the *Research Conflict of Interest Committee – Operating Guidelines* (Appendix B to the Medical Center's *Policies on Conflicts of Interest, Commitment and Consulting*). The conflict management plan shall be adopted by the RCOIC and agreed to by the principal investigator, and ratified by the IRB.

D. Appeals to the Senior Vice President and Vice Dean for Science. Appeals shall be in writing and submitted to the Office of Compliance. Appeals may be made by the Office of Compliance, the RCOIC, the Dean/CEO of the Medical Center, the Senior Vice President and Vice Dean for Science, or any Investigator on the project. The Office of Compliance will provide copies of the appeal to the Senior Vice President and Vice Dean for Science and the RCOIC Chair. Decisions of the Senior Vice President and Vice Dean for Science are final.

E. Timing. The review and evaluation of an Institutional Financial Interest as contemplated by this Policy shall be completed prior to the expenditure of any awarded funds for the human subjects' research project or any commencement of the project (including enrollment of any research subjects)

IV. **Examples of Institutional Conflicts of Interest**

Examples of matters arising under this Policy will be maintained and updated periodically on the Office of Compliance's webpage at <http://cmu.med.nyu.edu/>.

V. **Enforcement**

Violations of this Policy are subject to disciplinary action, up to and including termination of employment or association with the Medical Center, in accordance with the Medical Center's applicable disciplinary policies and procedures.

VI. **Administration**

A. Questions. Any questions relating to this Policy should be directed to the Office of Legal Counsel or the Office of Compliance.

B. Reporting. The RCOIC and the Office of Compliance shall provide reports of its activities under this Policy to the Senior Vice President and Vice Dean for Science on an annual basis.

PART THREE

FACULTY CONFLICTS OF COMMITMENT AND CONSULTING

Part Three consists of two policies: the *Policy on Faculty Conflicts of Commitment* and the *Policy on Faculty Consulting*. The policies in Part Three are intended, among other things, to restate for Medical Center faculty members the policies on conflict of commitment and faculty responsibility set forth in the NYU Faculty Handbook. The following table summarizes the application of these policies on Medical Center faculty members:

FACULTY CONFLICTS OF COMMITMENT AND CONSULTING SUMMARY TABLE				
<u>Role/Activity</u>	<u>Policy</u>	<u>Disclosure</u>	<u>Review and Evaluation</u>	<u>Policy & Criteria</u>
Faculty Engaged in non-NYU, non-Medical Center Activities	<i>Policy on Faculty Conflicts of Commitment</i>	<ul style="list-style-type: none"> • Annual disclosures, as required by the <i>Policy on Conflicts of Interest in Business Affairs</i> • Specific matters as they arise 	<p><i>Initial Collection:</i> Office of Compliance</p> <p><i>Final Review (Most Matters):</i> Senior Vice President and Vice Dean for Faculty, Education and Academic Affairs (in consultation with Department Chair)</p> <p><i>Final Review (Concurrent Faculty Appointments, Outside Managerial Positions and Acting as PI on Sponsored Programs that could be at NYU only):</i> Senior Vice President and Vice Dean for Faculty, Education and Academic Affairs and NYU Provost or NYU Senior Vice President for Health.</p>	A prohibited activity will not be permitted without the approvals specified in the policy.
Faculty Engaged in Outside Consulting	<i>Policy on Faculty Consulting</i>	<ul style="list-style-type: none"> • Annual disclosures, as required by the <i>Policy on Conflicts of Interest in Business Affairs</i> • Specific matters as they arise 	<p><i>Initial Collection:</i> Office of Compliance</p> <p><i>Final Review:</i> Senior Vice President and Vice Dean for Faculty, Education and Academic Affairs (in consultation with Department Chair)</p>	A prohibited activity will not be permitted without the approvals specified in the policy.

NYU LANGONE MEDICAL CENTER

POLICY ON FACULTY CONFLICTS OF COMMITMENT

Issue Date: April 1, 2009

Contents:

- I. Applicability
- II. General Policy
- III. Disclosure
- IV. Review and Evaluation
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 - 1. Significant Physical Presence
 - 2. Outside Activities
 - 3. Responsibilities Regarding Academic Freedom
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 - 7. Outside Consulting
- VI. Enforcement
- VII. Questions
- VIII. Additional Policies

I. Applicability

This Policy applies to all faculty members of the Medical Center (“Faculty Members”).

II. General Policy

All Faculty Members must avoid Conflicts of Commitment. A “**Conflict of Commitment**” occurs when a Faculty Member’s commitment to external activities - such as consulting, lecturing, acting as an expert witness, public service, service on a professional board or committee, or pro bono work - compromises his or her obligations to NYU and the Medical Center. Full-time Faculty Members owe their primary professional allegiance to NYU and the Medical Center, and their primary commitment of time and intellectual energies should be to the Medical Center’s teaching, research and clinical programs. An external activity which does not comply with this Policy results in a Conflict of Commitment.

III. Disclosure

A. General. As required under the Medical Center’s *Policy on Conflicts of Interest in Business Affairs*, a Faculty Member shall disclose in an annual disclosure form all external activities involving his or her professional competence and shall certify compliance with the Medical Center’s *Policies on Conflicts of Interest, Commitment and Consulting*. Such disclosure shall include all consulting and other external activities, including the entity(ies) for which such activities are to be performed and the nature, scope, duration and compensation for such activities. Disclosure submissions are required upon appointment, upon request of the Office of Compliance and annually thereafter. A Faculty Member must also disclose specific situations giving rise to a potential conflict between their personal interests and their

Medical Center responsibilities. The Medical Center's procedures for the review and evaluation of such disclosures are set forth in the *Policy on Conflicts of Interest in Business Affairs*.

B. Research and Sponsored Programs. In the event a Faculty Member participates in research or sponsored programs, the Faculty Member shall submit an investigator financial interest disclosure form as provided in the Medical Center's *Policy on Conflicts of Interest in Research and Sponsored Programs*. The Medical Center's procedures for the review and evaluation of such disclosures are set forth therein.

C. Confidentiality. All disclosures will be kept confidential and disclosed only on a need-to-know basis as required to perform the reviews and evaluations required by this Policy and the *Policies on Conflicts of Interest, Commitment and Consulting*.

IV. Review and Evaluation

A. The Office of Compliance shall collect all disclosures received from Faculty Members.

B. In cases where the Office of Compliance believes that a potential Conflict of Commitment exists, the Office of Compliance will submit the matter to the Faculty Member's Department Chair and to the Senior Vice President and Vice Dean for Faculty, Education and Academic Affairs of the Medical Center.

C. A Conflict of Commitment may exist whenever a Faculty Member (i) discloses an outside position such as a director, trustee, partner, senior executive, officer or employee or (ii) discloses receipt in the last year, or expectation of receipt in the next year, of compensation from consulting or other external activities (i.e., consulting fees, honoraria, lecture fees, other emoluments, stock, stock options, royalties or "in-kind" compensation directly or indirectly) (a) in excess of \$50,000 from any individual entity or (b) in excess of an aggregate of \$100,000 from all outside entities. Prior to such submission, the Office of Compliance will request the Faculty Member to certify that the external activity(ies) or interest(s) is consistent with this Policy, including specifically that the activities do not exceed an average of one day per seven-day week (or the equivalent of an eight-hour work day) as contemplated below.

D. The Senior Vice President and Vice Dean for Faculty, Education and Academic Affairs, in conference with the Faculty Member's Department Chair, is responsible for reviewing and evaluating each potential Conflict of Commitment involving a Faculty Member submitted by the Office of Compliance. The Vice Dean for Faculty, Education and Academic Affairs may refer Conflict of Commitment matters to the Business Conflict of Interest Committee (BCOIC) or to individual members of the BCOIC for an advisory opinion.

E. Except where this Policy explicitly provides for review by the Provost of NYU or the Senior Vice President for Health of NYU, decisions of the Senior Vice President and Vice Dean for Faculty, Education and Academic Affairs are final.

V. Policy and Discussion

1. *Faculty Members must maintain a significant physical presence on campus throughout each period while they are compensated by the Medical Center.*

A full-time appointment to be a Faculty Member at the Medical Center conveys an obligation for a Faculty Member to have a significant physical presence on campus at the Medical Center, to be accessible to students and staff, and to be available to interact with NYU and Medical Center colleagues throughout every period while he or she is receiving compensation from the Medical Center (i.e., holds a compensated appointment and is not on leave), unless his or her Department Chair and/or the Vice Dean

for Faculty, Education and Academic Affairs has granted specific prior approval for extended or frequent absences from campus. Fulfillment of these obligations requires a primary commitment of expertise, time, and energy.

Requests for field research and other reasons for absence from the Medical Center need to be approved by his or her Department Chair and be in accordance with policies and guidelines promulgated from time to time by the Vice Dean for Faculty, Education and Academic Affairs and the Senior Vice President and Vice Dean for Science of the Medical Center.

2. Faculty Members must not allow other professional or academic activities to detract from their primary allegiance to NYU and the Medical Center and should be guided and governed in their consideration of an offer of ancillary employment by their primary obligation of furthering the Medical Center's essential missions. In particular, outside activities which involve teaching at another institution require special disclosure and review.

Outside Activities Generally.

Outside professional or academic activities may detract from a Faculty Member's obligations to NYU and the Medical Center. For that reason, any outside activities must be consistent with the principles outlined in this Policy and in all of the Medical Center's *Policies on Conflicts of Interest, Commitment and Consulting*. In particular, when judging the appropriateness of such activities outside of NYU and the Medical Center, Faculty Members should consider the time commitment involved and the potential impact of these activities on the fulfillment of NYU's and the Medical Center's institutional goals.

In addition, Faculty Members receiving full-time compensation should not have outside executive or managerial responsibilities in private or public organizations nor act as a principal investigator at another institution (other than institutions in which the Medical Center has a formal affiliation) on sponsored projects that could be conducted at NYU or the Medical Center, without prior approval of his or her Department Chair, the Vice Dean for Faculty, Education and Academic Affairs, and the Provost of NYU or the Senior Vice President for Health of NYU.

Part-time Faculty Members may accept any outside employment that neither creates a conflict of interest nor interferes with any of their obligations to NYU or the Medical Center.

Outside Teaching Activities.

Of all the activities in which a Faculty Member might engage outside NYU or the Medical Center, teaching presents issues that require special attention because it competes most directly with NYU's core educational mission.

A Faculty Member may not accept a concurrent faculty appointment at another academic institution, even while on unpaid leave from the Medical Center, without prior written approval from the Vice Dean for Faculty, Education and Academic Affairs and the Provost of NYU or the Senior Vice President for Health of NYU.

All outside teaching activities require disclosure to and prior approval by the Vice Dean for Faculty, Education and Academic Affairs other than:

- (a) Delivering a limited number of lectures at other academic institutions, at conferences, or at public gatherings (with or without compensation);

- (b) Teaching summer courses, at NYU, the Medical Center or elsewhere, by Faculty Members not receiving other summer compensation for the period in question; and
- (c) Posting of uncompensated, non-interactive educational materials on a website.

The above exceptions are not absolute. For example, a Faculty Member should not teach courses identical to his or her NYU and Medical Center courses at another institution, even during a period when he or she is not compensated by the Medical Center, without prior disclosure, and if necessary, discussion with his or her Department and/or the Vice Dean for Faculty, Education and Academic Affairs.

These rules apply to full-time Faculty Members. Part-time Faculty Members are expected to disclose their teaching activities outside of NYU and the Medical Center when they are appointed and whenever a material change has occurred and to engage in teaching activities outside of NYU and the Medical Center only to the extent they do not interfere with any of their teaching obligations to NYU and the Medical Center. Part-time Faculty Members should also not teach courses designed for NYU or the Medical Center at another institution.

3. Faculty Members must foster an atmosphere of academic freedom by promoting the open and timely exchange of results of scholarly activities, ensuring that their advising of students and postdoctoral scholars is independent of personal commercial interests, and informing students and colleagues about outside obligations that might influence the free exchange of scholarly information between them and the Faculty Member.

Faculty must ensure that:

- (a) the results of research or scholarship undertaken at the Medical Center are disseminated on an open and timely basis to the broader scholarly community and public;
- (b) the academic activities of students and postdoctoral scholars are free from the outside personal interests of the Faculty Member; and
- (c) the work of students, postdoctoral scholars, staff and faculty collaborators is not inappropriately used in the course of a Faculty Member's outside obligations. To this end, Faculty Members should be open about their involvements with and obligations to outside third parties who could benefit from the work or ideas of their students, staff, and colleagues. Similarly, students, associates, and staff should have access to information about the sources of funds that support their research.

For further information see the *NYU Guidelines for Sponsored Research* in the NYU Faculty Handbook.

4. Appropriate use of NYU and Medical Center resources.

Medical Center facilities and other resources are provided to further the Medical Center's educational, administrative, research, clinical, and other goals. These resources may not be used for outside consulting or other commercial activities, except in a purely incidental manner. No personal use may adversely affect work performance nor add more than a negligible amount to the cost of these resources for the Medical Center. All such incidental or other personal use must be in accordance with the *Policies on Conflicts of Interest, Commitment and Consulting* and all other applicable NYU and Medical Center policies. The use of NYU and Medical Center confidential information is never permitted and shall never be considered purely incidental. The Medical Center will not take any special measures to ensure the security or privacy of any Faculty Member's work arising from a purely incidental or other personal use

of Medical Center's resources. If a Faculty Member has a question about whether an activity is permitted under this Policy, the Faculty Member should contact the Office of Compliance or his or her Department Chair.

5. Inventions created or discovered in the course of a Faculty Member's NYU and Medical Center activities or with more than incidental use of NYU or Medical Center resources must be disclosed and assigned to NYU on a timely basis. See NYU Statement of Policy on Intellectual Property.

The NYU Policy on Intellectual Property provides that (i) Faculty Member inventors must disclose on a timely basis the creation or discovery of all potentially patentable inventions created or discovered in the course of their NYU and Medical Center activities or with more than incidental use of NYU or Medical Center resources, (ii) ownership of such inventions must be assigned to NYU regardless of the source of funding, and (iii) Faculty Member inventors will share in royalties earned by NYU.

6. Permitted Time to Engage in External Activities

Full-time Faculty Members are permitted to spend no more than an average of one day per seven-day week (or the equivalent of an eight-hour work day) on outside consulting activities during any semester, or summer month, in which they are receiving full-time compensation from the Medical Center.

7. Outside Consulting

All full-time Faculty Members who engage in consulting and other external activities (including lecturing, acting as an expert witness, public service, service on a professional board or committee) must conduct the activities in accordance with the Medical Center's *Policy on Faculty Consulting*.

VI. **Enforcement**

Violations of this Policy are subject to disciplinary action, up to and including termination of employment or association with the Medical Center, in accordance with the Medical Center disciplinary policies and procedures applicable to the Faculty Member.

VII. **Questions**

Any questions relating to this Policy should be directed to the Office of Legal Counsel or the Office of Compliance.

VIII. **Additional Policies**

This Policy is intended to supplement, but not replace, other policies and guidelines applicable to the Faculty Member, including the conflict policies set forth in the NYU Faculty Handbook and elsewhere in the *Policies on Conflicts of Interest, Commitment and Consulting*.

NYU LANGONE MEDICAL CENTER

POLICY ON FACULTY CONSULTING

Issue Date: April 1, 2009

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I. Applicability

This Policy applies to all faculty members of the Medical Center (“Faculty Members”).

II. General Policy

A Faculty Member may use his or her professional competence to engage in consulting and other external activities (including lecturing, acting as an expert witness, public service, service on a professional board or committee) as long as such activities avoid Conflicts of Commitment and Conflicts of Interest. A “**Conflict of Commitment**” occurs when external activities undermine the Faculty Member’s primary professional commitment of time and intellectual energies to the Medical Center’s teaching, research and clinical programs. A “**Conflict of Interest**” exists when external activities influence or appear to influence a Faculty Member’s ability to promote objectively the best interests of the Medical Center. A consulting or other external activity which does not comply with this Policy results in a Conflict of Commitment or Conflict of Interest.

III. Disclosure

A. General. As required under the *Policy on Conflicts of Interest in Business Affairs*, a Faculty Member shall disclose in the annual disclosure form all outside activities involving his or her professional competence and shall certify compliance with the Medical Center’s *Policies on Conflicts of Interest, Commitment and Consulting*. Such disclosure shall include all consulting and other external activities, including the entity(ies) for which such activities are to be performed and the nature, scope, duration and compensation for such activities. Disclosure submissions are required upon appointment, upon request of the Office of Compliance, and annually thereafter. A Faculty Member must also disclose specific situations giving rise to a potential Conflict of Interest between their personal interests and their Medical Center responsibilities. The Medical Center’s procedures for the review and evaluation of such

disclosures and potential Conflicts of Interest arising therefrom are set forth in the *Policy on Conflicts of Interest in Business Affairs*.

B. Research and Sponsored Programs. In the event a Faculty Member participates in research or sponsored programs, the Faculty Member must submit an investigator financial interest disclosure form as provided in the *Policy on Conflicts of Interest in Research and Sponsored Programs*. The Medical Center's procedures for the review and evaluation of such disclosures and potential Conflicts of Interest arising therefrom are set forth therein.

C. Confidentiality. All disclosures will be kept confidential and disclosed only on a need-to-know basis as required to perform the reviews and evaluations required by this Policy and the *Policies on Conflicts of Interest, Commitment and Consulting*.

IV. Review and Evaluation

A. Under the *Policy on Conflicts of Interest in Business Affairs* and *Policy on Faculty Conflicts of Commitment*, the Office of Compliance is responsible for collecting each disclosure received from Faculty Members.

B. In cases where the Office of Compliance believes that a potential Conflict of Interest exists, the Office of Compliance will submit the matter to the Business Conflict of Interest Committee.

C. In cases where the Office of Compliance believes that a potential Conflict of Commitment exists, the Office of Compliance will submit the matter to the Faculty Member's Department Chair and to the Senior Vice President and Vice Dean for Faculty, Education and Academic Affairs of the Medical Center. A Conflict of Commitment may exist whenever a Faculty Member discloses receipt in the last year, or has expectations to receive in the next year, compensation from consulting or other external activities (i.e., consulting fees, honoraria, lecture fees, other emoluments, stock, stock options, royalties or "in-kind" compensation directly or indirectly) either (i) in excess of \$50,000 from any individual entity or (ii) in excess of an aggregate of \$100,000 from all outside entities. Prior to such submission, the Office of Compliance will request the Faculty Member to certify that the external activity(ies) is consistent with this Policy and the *Policy on Conflicts of Commitment*, including specifically that the activities do not exceed an average of one day per seven-day week (or the equivalent of an eight-hour work day) as contemplated below.

D. The Senior Vice President and Vice Dean for Faculty, Education and Academic Affairs, in conference with the Faculty Member's Department Chair, is responsible for reviewing and evaluating each potential Conflict of Commitment involving a Faculty Member submitted by the Office of Compliance. The Vice Dean for Faculty, Education and Academic Affairs may refer matters under this Policy to the Business Conflict of Interest Committee (BCOIC) or to individual members of the BCOIC for an advisory opinion.

E. Except where the Policy explicitly provides for review by the Provost of NYU or the Senior Vice President for Health of NYU, decisions of the Senior Vice President and Vice Dean for Faculty, Education and Academic Affairs are final.

V. Conflicts of Interest and Commitment

A Faculty Member's participation in outside consulting must be consistent with the Faculty Member's obligations under the *Policy on Conflicts of Interest in Business Affairs* and the *Policy on Faculty*

Conflicts of Commitment. Accordingly, all full-time Faculty Members who engage in consulting or other external activities are subject to the following:

A. Faculty Members have a primary obligation to serve the purposes to which the Medical Center is dedicated. As part of this obligation, each Faculty Member has a duty to organize his or her personal interests or activities to avoid the appearance that such personal interests or activities are influencing his or her ability to promote objectively the best interests of the Medical Center.

B. Full-time Faculty Members are permitted to spend no more than an average of one day per seven-day week (or the equivalent of an eight-hour work day) on consulting or other external activities during any semester, or summer month, in which they are receiving full-time compensation from the Medical Center.

C. Faculty Members are ordinarily not permitted to hold an executive or managerial position in a public or private organization. Any exceptions require prior written permission from the Department Chair, Senior Vice President and Vice Dean for Faculty, Education and Academic Affairs and from the Provost of NYU or the Senior Vice President for Health of NYU.

VI. **Use of NYU and Medical Center Resources**

Faculty Members may not use any NYU or Medical Center resources, including facilities, personnel, or equipment, except in a purely incidental way, as part of or in connection with their outside consulting activities. In particular, Faculty Members may not use NYU and Medical Center students, staff or postdoctoral scholars in any tasks that relate to the Faculty Member's consulting activities or for potential or real financial gain, without full disclosure and approval.

Inappropriate uses of NYU and Medical Center resources by Faculty Members also include, but are not limited to, the following:

- (a) Any use of NYU or Medical Center funding as part of or in connection with their consulting activities;
- (b) Any use of NYU or Medical Center confidential information (including all information acquired while conducting NYU or Medical Center business or research activities) as part of or in connection with their consulting activities;
- (c) Any use of the NYU or Medical Center name, or any NYU or Medical Center mark, symbol or logo as part of or in connection with their consulting activities;
- (d) Granting an outside entity access to other NYU or Medical Center resources including research results, materials or products generated from NYU or Medical Center teaching, research or clinical activities; and
- (e) Offering inappropriate inducements to outside entities in an attempt to unduly influence them in their dealings with NYU or the Medical Center.

VII. **Intellectual Property Obligations**

Prior to beginning any outside consulting activity, a Faculty Member shall inform the party for whom the consulting activities are to be performed of the *NYU Statement of Policy on Intellectual Property*, this Policy and the *Policies on Conflicts of Interest, Commitment and Consulting*, and the Faculty Member's

obligations under such policies. It is strongly encouraged that consulting agreements between the Faculty Member and the party for whom consulting activities are to be performed recognize NYU's rights and priority under such policies to the extent they apply. In the event a Faculty Member has questions regarding the intellectual property provisions of a consulting agreement, the Faculty Member should address the question to the Office of Industrial Liaison.

VIII. **Conflicts of Interest in Research and Sponsored Programs**

Faculty Members may not either (a) receive funds for Medical Center research from a party for whom the consulting activities are being performed or (b) engage in consulting activities for a party from whom funds are to be received for the Faculty Member's research, without prior disclosure, review and approval as required by the *Policy on Conflicts of Interest in Research and Sponsored Programs*.

IX. **No Liability Protection Afforded by NYU or the Medical Center**

Faculty Members must understand that risk and liability for injuries arising out of the Faculty Member's outside consulting is personal to the Faculty Member and does not accrue to NYU or the Medical Center. When entering into arrangements to engage in activities outside the scope of his or her employment, Faculty Members are encouraged to use personal legal counsel to ensure their own protection and compliance with applicable laws.

X. **Enforcement**

Violations of this Policy are subject to disciplinary action, up to and including termination of employment or association with the Medical Center, in accordance with the Medical Center disciplinary policies and procedures applicable to the respective Faculty Member.

XI. **Questions**

Any questions relating to this Policy should be directed to the Office of Legal Counsel or the Office of Compliance.

XII. **Additional Policies**

This Policy is intended to supplement, but not replace, other policies and guidelines applicable to the Faculty Member, including the conflict policies set forth in the NYU Faculty Handbook and elsewhere in the *Policies on Conflicts of Interest, Commitment and Consulting*.

APPENDIX A
TO
POLICIES ON CONFLICTS OF INTEREST, COMMITMENT AND CONSULTING

BUSINESS CONFLICT OF INTEREST COMMITTEE
OPERATING GUIDELINES

(Capitalized terms are defined in the Medical Center's *Policy on Conflicts of Interest in Business Affairs*)

I. **Governance**—The members of the Business Conflict of Interest Committee (BCOIC), including the Chair, are nominated and appointed by the Dean and CEO of the Medical Center. The Chair of the BCOIC will report to the Audit and Compliance Committee of the Board of Trustees regarding the BCOIC's activities. The BCOIC shall provide reports of its activities to the Dean/CEO annually or more frequently if requested.

II. **Members**—The BCOIC may include the following representation:

- the Executive Vice President and Vice Dean, Chief of Staff, of the Medical Center (or his or her designee)
- the Senior Vice President and Vice Dean for Education, Faculty and Academic Affairs of the Medical Center (or his or her designee)
- the Senior Vice President and Vice Dean for Science of the Medical Center (or his or her designee)
- the Senior Vice President and Vice Dean, General Counsel, of the Medical Center (or his or her designee)
- the Senior Vice President and Vice Dean for Human Resources of the Medical Center (or his or her designee)
- the Vice President for Medical Center Audit & Compliance (or his or her designee)

Recusal is required whenever any member has a conflict of interest (personal or due to Medical Center responsibilities) regarding any matter under review.

The BCOIC may invite other individuals to attend meetings as needed.

III. **General Responsibilities**

- A. The BCOIC shall review any matter arising under the Medical Center's *Policy on Conflicts of Interest in Business Affairs* submitted to it by the Office of Compliance.
- B. The BCOIC may also provide advice to the Vice Dean for Education, Faculty and Academic Affairs on matters arising under the Medical Center's *Policy on Faculty Conflicts of Commitment* and the Medical Center's *Policy on Faculty Consulting*.

- C. The BCOIC shall direct the Office of Compliance in the management and oversight of Conflicts of Interest.
- D. Through the use of case studies, the BCOIC will develop a standard approach to managing similar types of potential conflicts for which a standard approach is reasonable and appropriate.
- E. The BCOIC must report to the Audit and Compliance Committee of the Board of Trustees all findings it makes arising from its review and evaluation responsibilities under the *Policy on Conflicts of Interest in Business Affairs*.

IV. **Review and Evaluation Procedures**

- A. The BCOIC is responsible for reviewing and evaluating each Conflict of Interest matter involving an NYULMC Member submitted to it by the Office of Compliance pursuant to the *Policy on Conflicts of Interest in Business Affairs*.
- B. As provided in such *Policy*, if the BCOIC finds that a Conflict of Interest exists, the Medical Center will not approve the matter. An exception to the foregoing policy statement may be made only under a finding, after review of all material facts as to the interest and the matter, by the BCOIC that extraordinary circumstances merit an exception to such *Policy*. A finding of extraordinary circumstances will be made by the BCOIC only under a plan for managing and monitoring the Conflict of Interest which is fully consistent with the best interests of the Medical Center.
- C. In the event that the BCOIC approves a matter notwithstanding a Conflict of Interest, the BCOIC, with the advice of the Office of Compliance and the Office of Legal Counsel, shall provide for a conflict management plan (the “Plan”) that describes the financial interest, the conditions under which the activity may proceed, and the individuals subject to the Plan (the “Interested Parties”). Any changes in the Plan require the approval of the BCOIC.
- D. The Office of Compliance shall distribute copies of the Plan to the Interested Parties and the Dean/CEO. The Office of Compliance may also send the Plan to the Interested Parties’ Department Chair or other administrative superiors for informational and possibly management purposes.
- E. The BCOIC or the Office of Compliance may perform (or direct) audits to ensure compliance with the Plan.

APPENDIX B
TO
POLICIES ON CONFLICTS OF INTEREST, COMMITMENT AND CONSULTING

RESEARCH CONFLICT OF INTEREST COMMITTEE
OPERATING GUIDELINES

(Capitalized terms are defined in the *Policy on Conflicts of Interest in Research and Sponsored Programs* or the *Policy on Institutional Conflicts of Interest in Human Subjects Research*.)

I. **Research Conflict of Interest Committee (or RCOIC) Governance**—The RCOIC’s members, including the Chair, are nominated by the Senior Vice President and Vice Dean for Science of the Medical Center and are appointed by the Dean and CEO of the Medical Center. The Chair of the RCOIC and the Office of Compliance will report to the Senior Vice President and Vice Dean for Science regarding the RCOIC’s activities annually or more frequently if requested.

II. **RCOIC Members**—The RCOIC should consist of at least five (5) and no more than nine (9) members, each appointed for a three-year term. The RCOIC’s members shall be faculty members of the Medical Center, except that one (1) member of RCOIC may be from NYU but not from the Medical Center and one (1) member of RCOIC may be from outside of the NYU and Medical Center community. The RCOIC shall include (i) at least one faculty member who conducts Non-Human Subjects Research; (ii) at least one faculty member who conducts Human Subjects Research; and (iii) at least one member of the Medical Center’s IRB. Recusal is required whenever any member has a conflict of interest (personal or due to Medical Center responsibilities) regarding any matter under review.

III. **RCOIC Meetings**

A. Meetings of the RCOIC shall be scheduled monthly and held as needed.

B. The following Medical Center individuals shall be invited to attend all non-executive meetings of the RCOIC: (i) representative(s) from the Office of Compliance; (ii) representative(s) from the Office of Science & Research, (iii) a representative of the Office of Industrial Liaison, (iv) a representative from the IRB’s staff; and (v) a representative from the Office of Legal Counsel. The RCOIC and the Office of Compliance may also invite individuals to attend meetings as situations warrant. Non-RCOIC members are not entitled to a vote on RCOIC matters.

C. Executive meetings of the RCOIC may be called by the Chair of the RCOIC or the Office of Compliance for investigations and other special matters. Only members of the RCOIC and representatives from the Office of Compliance and the Office of Legal Counsel shall be invited to attend executive meetings of the RCOIC.

D. Each RCOIC member shall have one vote. Actions of the RCOIC shall require a majority of the votes cast at any meeting in which a quorum is present. The presence of an actual majority of the members of the RCOIC shall constitute a quorum and shall be necessary to conduct the business of the RCOIC. RCOIC meetings may be held in person or by teleconference. Minutes shall be kept of all meetings of the RCOIC and approved at subsequent meetings of the RCOIC.

E. The RCOIC may also act by unanimous consent electronically, including via e-mail correspondence, without a scheduled meeting. Any such actions shall be entered into the minutes at the next scheduled meeting of the RCOIC.

F. The Chair of the RCOIC may act for the RCOIC on behalf of the full RCOIC, provided that such act is conditional pending ratification by the RCOIC at the next scheduled meeting. The Chair of the RCOIC may take this temporary action only in the event a project will lapse or otherwise be materially compromised if a delay is required until the next scheduled meeting of the RCOIC.

G. To the limited extent permitted by the *Policy on Conflicts of Interest in Research and Sponsored Programs*, the Office of Compliance may make determinations on behalf of the RCOIC. When the Office of Compliance makes any such determination, the Office of Compliance shall report such action to the RCOIC and the RCOIC shall enter such act into the minutes at the next scheduled meeting.

H. All information disclosed at or in connection with any RCOIC meeting will be kept confidential by all RCOIC members and invitees and used only as contemplated in these Operating Guidelines.

IV. **Responsibilities**

A. The RCOIC shall review any initial disclosure of a Significant Financial Interest under the *Policy on Conflicts of Interest in Research and Sponsored Programs* or Institutional Financial Interest under the *Policy on Institutional Conflicts of Interest in Human Subjects Research*, and any other matter referred to it by the Office of Compliance.

B. The RCOIC's primary responsibility is to make a determination on any matter submitted to it by the Office of Compliance on whether Compelling Circumstances exist that justify (i) an Investigator's participation in the Sponsored Project notwithstanding a disclosed Financial Interest or (ii) the Medical Center's participation in a Human Subjects Research project notwithstanding an Institutional Financial Interest. The RCOIC shall make and document its determinations.

C. The RCOIC shall make a determination that Compelling Circumstances exist to justify participation only if the RCOIC adopts a conflict management plan (the "Plan") which maintains research integrity and serves the best interests of subjects. The Plan shall describe the nature of the financial interest, the conditions under which the activity may proceed and the individuals, including the principal investigator, subject to the Plan (the "Interested Parties"). A Plan permitting an activity notwithstanding a Significant Financial Interest/Institutional Conflict of Interest should contain an additional paragraph describing the depth and frequency of any compliance audits that are required by the Plan. The RCOIC shall use its best efforts to develop a standard approach to managing those types of interests for which a standard approach is reasonable and appropriate. Any changes in the Plan (other than by the Senior Vice President and Vice Dean for Science under Section VII below) require the approval of the RCOIC.

D. The review and evaluation of any submission to the RCOIC must be completed prior to the expenditure of any awarded funds for the applicable Sponsored Project or its commencement (including any enrollment of research subjects).

V. **Compelling Circumstances Test**— A finding of Compelling Circumstances will be exceptional, made only after a review of the totality of the circumstances, and made only where the RCOIC is satisfied that a Plan to mitigate any effects of the Significant Financial Interest/Institutional Conflict of Interest can and will be implemented. The following list of factors to consider may (or may not) be used by the RCOIC, at its discretion, in evaluating whether Compelling Circumstances are present:

- A. whether basic academic values are upheld, an open academic environment is maintained, the research is appropriate to the mission of the Medical Center, and the research is of a fundamental or basic nature;
- B. the nature and amount of the disclosed interest, how closely the interest is related to the research, the control or influence such relationship or interest might have over the Research Sponsor's or Financially-Interested Company's decisions, and the extent to which the research results could be influenced by the financial interest;
- C. whether the research is essential to maintain the continuity of a research effort related to NYU's rights in intellectual property covering a product or process to be used in the research;
- D. the potential gains to patients and the community in the immediate and long-term future in the event the research is successful;
- E. any unique expertise of the Investigator (e.g. inventorship, experience, special insights, knowledge, perseverance, laboratory resources or a need for a special patient population) that may make his or her involvement essential, including the degree to which the safety or effectiveness of the research might be compromised without that individual;
- F. restrictions, if any, on publications, presentations or other disseminations related to or referencing the research or the research results;
- G. whether the risks to Human Subjects Research are sufficiently low and disposition may be similar to or identical with disposition for a Non-Human Subjects Research project;
- H. the steps proposed by the Investigator for effective oversight and management of the financial interests;
- I. what role students, trainees, and junior faculty and staff will play and whether such role is appropriate and free from exploitation; and
- J. (for Institutional Financial Interests in Human Subjects Research only) whether the Medical Center is uniquely qualified (by special facilities or equipment, unique patient population, qualifications of its investigators, etc.) to conduct the research and safeguard the human subjects in the Research.

Compelling Circumstances will not normally be found to justify participation in a clinical trial if participation gives rise to a Conflict of Interest or Institutional Conflict of Interest.

VI. **Management Strategies**—In its deliberations, the RCOIC shall consider the following management strategies for inclusion in the Plan for both individual and institutional conflicts of interest:

- A. Restriction from holding the Outside Position;
- B. Reduction, divestiture or elimination of the Financial Interest;
- C. Disclosure of the interests: to others working on the research; to the Research Sponsor; to federal or state government officials as required by law; in any substantive public communication related to or referencing the research or the research results (including publications, presentations and

other disseminations, whether oral or written); and to research subjects in the informed consent documents in an IRB-agreed form.

Generally, disclosures should be sufficiently specific to indicate whether the financial interest giving rise to the potential conflict is one of the following arrangements, if applicable: (a) consulting income, (b) royalties (including an institutionally-defined inventor's share), (c) equity interests, or (d) an outside, fiduciary position. Such disclosure should also indicate that the conflict has been disclosed and evaluated and is being managed by the Medical Center.

Disclosures to subjects will include (a) a clear reference to the presence of the conflicting interest, (b) an explanation of the fact that the financial interest has been reviewed by the RCOIC and approved subject to management and oversight, (c) a statement by both the Committee and the IRB that there is little increased risk to the welfare of the subject or to scientific quality of the research, and (d) an explanation that additional information would be provided to the research subjects upon request.

- D. Disqualification or restriction of the conflicted Investigator's participation in all or relevant portions of the research activity;
- E. Revision of study design to address potential bias from interests;
- F. Periodic or annual reports to the RCOIC certifying compliance with the applicable Plan;
- G. Appointment of a review committee to receive periodic reports regarding implementation of the Plan, or of individual(s) with sufficient independence and expertise to evaluate the research and its progress to oversee and monitor the entire project or of the research data. The review committee or the individuals may be from within or outside the Medical Center; and
- H. [for institutional conflicts only] Limitation of research to a non-primary research site and/or not serving as the coordinating site.

The RCOIC shall be mindful that the data integrity risks of Non-Human Subjects Research are the same as those in Human Subjects Research.

VII. **Appeals**—Determinations of the RCOIC may be appealed to the Senior Vice President and Vice Dean for Science. Appeal must be in writing and be submitted to the Office of Compliance. Appeals may be made by the Office of Compliance, the RCOIC, Vice Dean for Science, the Investigator with the Financial Interest, or any other Interested Parties. The Office of Compliance will provide copies to the Vice Dean for Science and the RCOIC Chair. Decisions of the Vice Dean for Science are final and shall be submitted in writing by the Office of Compliance to the RCOIC or the IRB (if applicable), and the Investigator's Department Chair. If the Vice Dean for Science modifies the RCOIC's determination, the Office of Compliance shall modify and reissue the Plan.

VIII. **Comparative Authority of RCOIC and IRB / IACUC** —Neither the IRB nor IACUC may approve research protocols referred to the RCOIC that have not been recommended for approval by the RCOIC or approve monitoring procedures or other conditions that are less restrictive than those imposed by the RCOIC. No authorization granted by the RCOIC may supersede the authority of the IRB or the IACUC and both the IRB and the IACUC may modify the Plan to impose more stringent restrictions than those imposed by the RCOIC.