

# New York University

## UNIVERSITY POLICIES

<b>Title:</b>	NYU Policy on Academic Conflict of Interest and Conflict of Commitment
<b>Effective Date:</b>	September 2013
<b>Supersedes:</b>	NYU Policy on Academic Conflict of Interest and Conflict of Commitment, August 24, 2012
<b>Issuing Authority:</b>	University Provost
<b>Responsible Officer:</b>	Senior Vice Provost for Research

### **Purpose of this Policy**

The purpose of this policy is to establish consistent guidelines for Academic Conflict of Interest and Conflict of Commitment.

### **Who Needs to Know this Policy**

Faculty, administrators and staff in the NYU Academic Community

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## I. GENERAL PRINCIPLES

New York University (NYU) believes that a great university should be engaged in the world and should actively foster the transfer of knowledge gained in scholarship and research for the benefit of the public. NYU encourages its faculty to serve these goals through their primary commitment to engaging in teaching, research, including sponsored research, and collegial support activities that are consonant with our values as an institution of higher education. Insofar as is consistent with that commitment, it also is appropriate and often desirable for faculty members to participate in public and private activities beyond their NYU association by engaging in other professional and academic activities including public service, *pro bono* work and consulting activities that may benefit the participants, NYU, and the larger public. Normally it is expected that there will be no conflict between faculty commitment to NYU and other activities in which faculty members may engage, that faculty and Investigators (as defined below) will conduct their affairs so as to avoid or minimize conflicts of interest, and that should there be any actual, potential or appearance of conflicts between the individual's private interests and his or her professional obligations to NYU, the faculty member or Investigator will promptly disclose and resolve any issues before engaging in the activities.

NYU recognizes, however, that in undertaking activities as a part of a primary commitment to NYU or in outside endeavors, a divergence can occur between the personal interests of a faculty member or an Investigator and his or her professional obligations to NYU, in which case a conflict of commitment or conflict of interest can arise.

The purpose of this policy, including the Addendum on Conflicts of Interest in Research and Other Sponsored Projects, is to assist the faculty in determining whether and to what extent such other activities may conflict with the faculty's primary commitment to teaching, research and collegial responsibilities; to educate faculty and Investigators about situations that generate the potential for conflicts of interest or conflicts of commitment; to clarify expectations about disclosing interests and activities that might result in conflicts; to identify means to manage, reduce or eliminate such conflicts; and to promote the best interests of students and others whose work depends on the direction of faculty members and Investigators.

Every NYU faculty member and Investigator has an obligation to become familiar with and abide by the provisions of this policy. If a faculty member or Investigator has a question about whether an activity is permitted under this policy, the faculty member or Investigator should disclose the potential or appearance of conflict to and seek guidance from his or her department chair or School Dean, or the Office of the Provost (the Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing), or the Office of the General Counsel.

This policy covers conflicts of commitment and conflicts of interest. While this policy is of general applicability to faculty and Investigators, the Addendum on Conflicts of Interest in Research and Other Sponsored Projects, which is appended hereto as Exhibit B, includes specific provisions regarding conflicts of interest arising in connection with Research and Other Sponsored Projects. The Addendum on Conflicts of Interest in Research and Other Sponsored Projects, without reference to the other provisions of this policy or other NYU policies, is intended to meet NYU's obligations to maintain a policy on financial conflicts of interest in research funded by federal sponsoring agencies (including the Public Health Service of the U.S. Department of Health and Human Services and the National Science Foundation).

For purposes of this policy: (a) references to the "Provost" means the "Provost or his or her designee; and (b) references to the "Executive Vice President for Health" means "the "Executive Vice President for Health or his or her designee."

Individual Schools may wish to supplement this policy with policies applicable to their faculty and/or Investigators. To ensure consistency with NYU policies, such School policies must be approved by the Provost (the Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing).

## II. POLICY DEFINITIONS

A **Conflict of Commitment**, as discussed in greater detail in Section III, occurs when a faculty member's Outside Activities compromise or may compromise his or her ability to meet the faculty member's obligations to NYU.

A **Conflict of Interest**, as discussed in greater detail in Section IV and in the Addendum on Conflicts of Interest in Research and Other Sponsored Projects, means any circumstance in which the personal, professional, financial or other interests of an individual (including the Immediate Family Members of the individual) may potentially or actually diverge from, or may be reasonably perceived as potentially or actually diverging from, his or her professional obligations to NYU and the interests of NYU. A Conflict of Interest may exist whenever an independent observer might reasonably question

whether the individual's professional actions or decisions, including the ethical and objective conduct of scholarship, research or clinical care, are determined by considerations of personal gain, financial or otherwise. A conflict of interest under the Addendum on Conflicts of Interest in Research and Other Sponsored Projects constitutes a Conflict of Interest under this policy.

**Consulting** refers to any remunerated Outside Activity involving an individual's professional competence.

**Employment/Management/Fiduciary Role** means a position involving service, in either a personal or representative capacity, as an employee, executive, manager, officer, director, trustee, or equivalent in a business, enterprise or entity other than NYU or an entity that is 50% or more owned or controlled by NYU.

**Entity** includes the entity itself and entities that own or control, are owned or controlled by or are under common ownership or control with the entity, with ownership and control defined as a 50% or greater direct or indirect interest.

**Immediate Family Members** include an individual's spouse or domestic partner or person in a civil union or similar relationship, dependent children, and any other family members residing in the same household.

**Investigator** means the principal investigator or program director, and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of Research and Other Sponsored Projects, or who proposes funding for the Research and Other Sponsored Projects, at or under the auspices of NYU. For purposes of this policy, other than for the Addendum on Conflicts of Interest in Research and Other Sponsored Projects, Investigator only includes members of the University Community. Most, but not all, Investigators are NYU faculty members.

**NYU** includes the Schools and other units of NYU, NYU's Global Network University sites, and all University Affiliates (as each term is defined in NYU's Developing University Policies, as amended from time to time).

**Outside Activities** include any external Consulting or other business activities and external professional or academic endeavors, such as public service or *pro bono* work, performed outside of the faculty member's appointment to NYU or an Investigator's employment or association with NYU.

**Ownership Interest** means holding a financial or ownership interest in a business or entity, including stock, stock option, warrant, convertible debt, partnership interest, or LLP/LLC interest, or other ownership interest or right to obtain an ownership interest. The value of an Ownership Interest is determined through reference to public prices or other reasonable measures of fair market value where public prices are not available.

**Remuneration** includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid editorial or authorship activities).

Income for scholarly and professional activities performed in connection with a faculty member's appointment to NYU from seminars, lectures, teaching engagements or service on advisory committees or review panels sponsored by a federal, state, or local government agency, or an

institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education, for scholarly and professional activities performed in connection with a faculty member's appointment to NYU, such as lectures or seminars, editorial or authorship activities, service on advisory committees or review panels (including professional associations), are **excluded** from the definition of Remuneration.

**Research and Other Sponsored Projects** means any research project conducted at or under the auspices of NYU, whether or not externally funded, and any externally funded training or professional service project conducted at or under the auspices of NYU. Research and Other Sponsored Projects includes any systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge, including basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test, drug or device), and non-research projects such as training, clinical services, educational conferences, exhibitions, performances, archives, workshops, and library projects for which external funding is received. Research and Other Sponsored Projects includes any such activity for which funding is available from external sources through a grant, contract or agreement, including, but not limited to, research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects and research resources awards.

**School** means each NYU school, college and institute that functions similarly to a school or college (such as IFA, ISAW, Courant, CUSP, and SoE), each NYU comprehensive campus (such as New York, Abu Dhabi, Shanghai) and also may include for purposes of this policy other global sites as designated by the Provost.

**School Dean** means the dean, or his or her designee, of each NYU school and college, the director or each NYU institute that functions similarly to a school or college (such as IFA, ISAW, Courant and CUSP) and the Vice Chancellor of each NYU comprehensive campus (such as New York and Abu Dhabi). In the case of other NYU global sites that have faculty and/or Investigators, the Provost may designate someone to fulfill some or all of the duties of a School Dean as described herein with respect to such global sites.

**University Community** means NYU faculty, including visiting faculty; researchers, including persons participating in research at or under the auspices of NYU; employees; professional staff, including medical, dental and nursing staff; volunteers; fellows, trainees and post-doctoral appointees; students; and consultants, vendors and contractors.

### **III. CONFLICT OF COMMITMENT**

#### **A. Definition**

A Conflict of Commitment occurs when a faculty member's Outside Activities compromise or may compromise his or her ability to meet the faculty member's obligations to NYU.

Full-time NYU faculty members owe their primary professional allegiance to NYU, and their primary commitment of time and intellectual energies should be to NYU's teaching, research, and clinical programs.

The specific responsibilities and professional activities that constitute an appropriate primary commitment to NYU will differ across Schools, departments and units, but they should be based on a general understanding between the faculty member and his or her department chair and/or School Dean. Even with such understandings in place, however, attempts of faculty to balance NYU responsibilities with Outside Activities can result in conflicts regarding allocation of time and energies.

Normally, it is expected that there will be no Conflict of Commitment between faculty commitment to NYU and other activities in which faculty members may engage. Furthermore, to the extent any questions of possible Conflict of Commitment arise, it is anticipated that the faculty member will quickly resolve the issues.

Outside Activities that do not constitute a Conflict of Commitment are permissible only if they also do not result in an impermissible Conflict of Interest (as discussed in Section IV and the Addendum for Conflicts of Interest in Research and Other Sponsored Projects attached to this policy as Exhibit B) and are in accordance with all NYU policies, including this policy and policies of the applicable School.

## B. Policy and Discussion

*(1) Faculty must maintain a significant physical presence on their assigned campus throughout each semester or summer period while they are compensated by NYU.*

A full-time appointment conveys an obligation for a faculty member to have a significant physical presence on his or her assigned campus (e.g., New York, Abu Dhabi or other global campus), to be accessible to students and staff, and to be available to interact with NYU colleagues on that campus throughout every semester or summer period while the faculty member is receiving compensation from NYU (i.e., holds a compensated appointment and is not on leave), unless the department chair and/or School Dean 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.

Because requirements for field research and other reasons for absence from campus differ across NYU, Schools and departments may define for their faculties what qualifies as inappropriate, extended, or frequent absences.

*(2) Faculty must not allow Outside Activities to detract from their primary allegiance to NYU and should be guided and governed in their consideration of an offer of ancillary employment or other Outside Activities by their primary obligation of furthering NYU's essential missions. Appointment as a full-time faculty member is inconsistent with engaging in significant Outside Activities.*

Full-time faculty 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 Activities during any semester or summer months in which they receive compensation from NYU. Uncompensated scholarly and professional activities performed in connection with a faculty member's appointment to NYU, such as lectures or seminars sponsored by governmental or non-profit entities, service on advisory committees or review panels for government or non-profit entities, including professional associations, and service on the editorial board of a journal in the field of the faculty member's appointment, may be excluded from the definition of Outside Activities by the School Dean or the Provost (the Executive Vice President

for Health in the case of the Schools of Medicine, Dentistry and Nursing) for purposes of this paragraph.

In addition, full-time faculty members may not have executive or managerial responsibilities in a private or public entity outside of NYU.

Exceptions to the prohibitions against engaging in Outside Activities more than one day per seven-day week or having executive or managerial responsibilities in a private or public entity outside of NYU limitation are rare (and usually time limited where granted) and may be made only with the prior written approval of the School Dean and Provost (the Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing).

Outside Activities may detract from a faculty member's obligations to NYU. For that reason, Outside Activities must be consistent with the principles outlined in this policy and other applicable NYU policies. In particular, when judging the appropriateness of any such Outside Activity, faculty members must consider the time commitment involved and the potential impact of such Outside Activity, together with all of the faculty member's other Outside Activities, on the fulfillment of NYU's institutional goals.

Part-time faculty members may accept outside employment as long as it does not create a Conflict of Interest or otherwise interfere with any of their obligations to NYU.

#### **IV. CONFLICT OF INTEREST**

##### **A. Definition**

A Conflict of Interest means any circumstance in which the personal, professional, financial or other interests of an individual (including Immediate Family Members of the individual), may potentially or actually diverge from, or may be reasonably perceived as potentially or actually diverging from, his or her professional obligations to NYU and the interests of NYU. A Conflict of Interest may exist whenever an independent observer might reasonably question whether the individual's professional actions or decisions, including the ethical and objective conduct of scholarship, research or clinical care, are determined by considerations of personal gain, financial or otherwise.

##### **B. Policy and Discussion**

NYU is committed to operating in a highly ethical manner and in compliance with legal and regulatory requirements. Undisclosed or inappropriate Conflicts of Interest can compromise the integrity of NYU, can reflect negatively on faculty and Investigators, and can result in financial and other sanctions on NYU. It is therefore the policy of NYU that Conflicts of Interest, including actual, potential and appearances of conflicts, be disclosed (see Section V.A below) and permitted only in appropriate cases, after being evaluated in accordance with this policy and managed to the extent determined advisable (see Section V.B below). Faculty or Investigators who are unclear as to whether a matter must be disclosed should err on the side of disclosure.

NYU has broad power to require disclosures of Conflicts of Interest to determine whether a Conflict of Interest exists, to investigate Conflict of Interests, to manage or eliminate Conflicts of Interest, to impose appropriate sanctions on faculty and Investigators who violate this policy, to release

information about Conflicts of Interest and to require faculty and Investigators to take Conflict of Interest training. By way of example, the types of management actions that NYU may take in response to a Conflict of Interest include: reviewing and, where appropriate, monitoring the conflict; imposing conditions or restrictions intended to manage, reduce or eliminate such conflict; requiring disclosure of the conflict or of additional information; obtaining background documents; prohibiting a conflicted person from involvement, including exercising personal influence, in connection with a matter; obtaining waivers, consents and/or authorizations; appointing an oversight body to monitor the conflict or other activities; requiring relinquishment of interests and/or restructuring or severance of relationships that contribute to the conflict. In addition, NYU can eliminate the conflict, as for example by prohibiting a faculty member or an Investigator from participating in the activity or by requiring action that eliminates the conflict as a condition of participating in an activity.

### C. Types of Conflict of Interest

A Conflict of Interest can arise in numerous situations. The following discusses some of the more common types, although Conflicts of Interest may arise in varying circumstances not encompassed in the categories below. This policy applies to any circumstance that may constitute a Conflict of Interest, regardless of whether specifically described herein, and regardless of whether it is effectuated directly or indirectly. For example, while an individual's personal interests are defined to include only those of the person and his or her Immediate Family Members, there also may be situations where the interests of other persons, such as a close friend or other family member, create a Conflict of Interest.

Unless otherwise specifically stated, a faculty member or an Investigator may not engage in an activity prohibited by this Section IV.C. unless the activity is expressly permitted in the faculty member's or Investigator's employment contract with NYU or such activity is approved in advance in writing by the School Dean and Provost (the Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing). Any such approval may be subject to a plan to manage, reduce or eliminate the Conflict of Interest.

In addition, all permissible activities must be in accordance with all NYU policies, including this policy and policies of the relevant School.

(1) Outside Activities and Other Personal Activities. Faculty must not allow Outside Activities or other personal activities to detract from their primary allegiance to NYU, as discussed in Section III relating to Conflict of Commitment. In addition, faculty and Investigators must undertake their Outside Activities and other personal activities in compliance with all NYU policies, including this policy and policies of the relevant School. In particular, a faculty member's Outside Activities that involve teaching at another institution require special disclosure and review.

#### (a) Outside Activities and Other Personal Activities Generally

The following Outside Activities and other personal activities create a Conflict of Interest:

- (i) Competing, directly or indirectly, with NYU in the provision, purchase or sale of any property, goods or services or in other activities in which NYU is or might reasonably and appropriately become engaged; and

(ii) Appropriating or diverting a business or financial opportunity that the person knows or should know that NYU is pursuing or is considering pursuing or reasonably might be interested in pursuing if it were aware of the opportunity; and

(iii) Soliciting business that the person knows or should know would or might disturb an existing professional or business relationship that NYU has with any member of the University Community or outside entity.

(b) Outside Research Activities

Full-time faculty members and full-time Investigators may not act as a principal investigator under the auspices of another institution. All permissible outside research also must be in accordance with all NYU policies, including this policy and policies of the relevant School. See in particular the Addendum for Conflicts of Interest in Research and Other Sponsored Projects attached to this policy as Exhibit B.

(c) Outside Teaching Activities

A teaching engagement outside of NYU competes directly with NYU's core educational mission. Accordingly, a faculty member may not accept a concurrent faculty appointment at another academic institution; provided, however, that a faculty member may accept a concurrent faculty appointment at another academic institution while on unpaid leave from NYU with the prior approval of his or her School Dean.

All Outside Activities involving teaching require prior approval from the School Dean, other than:

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

(ii) Teaching summer courses, at NYU or elsewhere, by faculty not receiving other summer compensation from NYU for the period in question; and

(iii) Posting of uncompensated, non-interactive educational materials on a website.

The above exceptions are not absolute. For example, faculty should not teach courses designed for NYU at another institution or in connection with non-NYU distance learning ventures, even during a period when they are not compensated by NYU, without prior consultation and opportunity for comment by the department chair and/or School Dean.

These rules with respect to outside teaching activities apply primarily to full-time faculty. Part-time faculty members are expected to disclose their teaching activities outside of NYU as part of their appointment and whenever a material change has occurred and to engage in teaching activities outside of NYU only to the extent they do not interfere with any of their teaching obligations to NYU. In addition, the provisions cited above regarding teaching courses designed for NYU outside of NYU apply to part-time faculty as well.

(d) Requirements Related to Permissible Outside Activities, including Consulting, by NYU Faculty and Investigators

All faculty and Investigators who engage in Outside Activities, including Consulting, must conduct the activities in accordance with the following unless otherwise approved in accordance with this policy:

(i) The Outside Activities must be consistent with all NYU policies, including this policy and policies of the relevant School.

(ii) The Outside Activities of full-time faculty may not constitute a Conflict of Commitment as discussed in Section III above.

(iii) Faculty and Investigators must disclose in writing to NYU all Outside Activities, including the entity(ies) for which activities are to be performed and the nature, scope, duration and compensation for such activities, in accordance with NYU policies, including this policy and policies of the relevant School. Such Outside Activities must not constitute a Conflict of Interest without prior disclosure, review, approval and adherence to any required management plan.

(iv) Prior to beginning any Consulting, faculty and Investigators must inform the party for whom the Consulting is to be performed of NYU's intellectual property policies, including its Statement of Policy on Patents, and this policy, and the obligations of the faculty member and/or Investigator under such policies. It is strongly encouraged that faculty and Investigators obtain recognition in any Consulting agreement of NYU's rights and priorities under such policies to the extent they apply.

(v) Faculty and Investigators may not use NYU resources, including facilities, personnel or equipment, except in a purely incidental way, as part of or in connection with their Outside Activities. Use of NYU funding, NYU intellectual property and NYU confidential information is never incidental and may not be used as part of or in connection with Outside Activities. In particular, faculty and Investigators may not use NYU students, staff or postdoctoral scholars in any tasks that relate to the Outside Activities of the faculty member and/or Investigator or for potential or real financial gain.

(vi) Faculty and Investigators may not use the NYU name, or any NYU mark, symbol or logo, as part of or in connection with Outside Activities, other than reference to their NYU affiliation for identification purposes.

(vii) Faculty and Investigators must make it clear that their Outside Activities are personal, NYU has no involvement in or liability for such activities and NYU is not endorsing such activities.

(viii) Faculty and Investigators may not grant any outside person or entity access to NYU resources, including research results and materials or products generated from NYU teaching or research activities.

(ix) Faculty and Investigators may not make or offer inappropriate inducements or take actions that are illegal or unethical in connection with their Outside Activities.

(x) Faculty and Investigators may not either (i) receive funds for the faculty member's and/or Investigator's NYU research from a party for whom compensated Outside Activities are being performed or (ii) engage in compensated Outside Activities for a party from whom funds are to be received for the faculty member's or Investigator's NYU research, without prior disclosure, review, approval and adherence to any required management plan.

(xi) NYU has no responsibility or liability for the Outside Activities of faculty or Investigators. Faculty and Investigators are encouraged to consider all risks before undertaking Outside Activities. NYU insurance coverages do not protect faculty and Investigators engaged in Outside Activities.

(2) Scholarship and Other Academic Activities. The heart of a university is its commitment to academic values and the failure of faculty and Investigators to carry on scholarship and other academic activities in an ethical and appropriate manner can damage NYU's reputation and otherwise harm the NYU community, creating a Conflict of Interest. Consistent with NYU's mission and its prevailing academic ethos, faculty and Investigators are expected to foster an atmosphere of academic freedom by promoting the open and timely exchange of results of scholarly activities, ensuring that their advising of students, fellows, trainees and postdoctoral appointees 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 or Investigator.

Faculty and Investigators must ensure that:

- (a) The results of research or scholarship undertaken at NYU are disseminated on an open and timely basis to the broader scholarly community and public; and
- (b) The academic activities of student, fellows, trainees and postdoctoral appointees are free from the outside personal interests of the faculty member or Investigator; and
- (c) The work of students, fellows, trainees, postdoctoral appointees, and others is not inappropriately used in the course of a faculty member's or Investigator's outside obligations. To this end, faculty members and Investigators 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, staff and faculty collaborators should have access to information about the sources of funds that support their research and their contributions to such research should be properly credited; and
- (d) They have made a sufficient contribution under pertinent professional academic standards to warrant the authorship credit to be given them; and they must not permit their

identification as an author of a publication that they know or should know was written by sources who are not properly identified and credited (i.e., ghostwritten).

For further information see the NYU Guidelines for Sponsored Research (Faculty Handbook), <http://www.nyu.edu/about/policies-guidelines-compliance/policies-and-guidelines/faculty-handbook.html>.

(3) Activities Creating a Conflict of Interest. The following activities create a Conflict of Interest

- (a) Improper Use of NYU Resources. NYU facilities, personnel and other resources are provided to further NYU's educational, administrative, research, clinical and other goals. These resources may not be used for personal use, including Outside Activities, except in a purely incidental manner. Personal use may not adversely affect work performance or add more than a negligible amount to the cost of these resources for NYU. All such incidental or other personal use must be in accordance with all NYU policies, including this policy and policies of the relevant School. The personal use, including in Outside Activities, of NYU funding or NYU intellectual property is never permitted and is never considered purely incidental. NYU does not ensure the security or privacy of any faculty work arising from personal use of NYU resources.
- (b) Obtaining, Using or Disclosing NYU Confidential Information.
  - (i) Obtaining, using or disclosing NYU confidential information for direct or indirect personal interest, profit or advantage or, for a purpose that may be detrimental to NYU.
  - (ii) Use of NYU confidential information for a purpose that is not authorized by NYU or disclosure of NYU confidential information to a person who or entity that is not authorized by NYU to receive it.

For purposes of this policy, NYU confidential information includes, but is not limited to: medical, personnel, security, academic, background check, conflict of interest, identifiable biometric records and other non-public information about individuals; business records; contracts and business terms; business and donor relationships; computer system passwords and security codes; proprietary and competitively sensitive information, including non-public information about anticipated material requirements, price actions, programs, and selection of contractors and subcontractors in advance of official announcements; unpublished grant proposals, non-public research data, manuscripts and correspondence; non-public financial, procurement, health-safety, audit, insurance and claims information; and non-public information relating to internal investigations, pre-litigation and litigation and administrative agency charges, audits and inquiries; and other information whose confidentiality is protected by law or NYU policies.

- (c) Failing to Disclose and Assign Inventions and Discoveries. Inventions and discoveries by faculty members, Investigators and others subject to NYU's *Statement of Policy on Patents*, <http://www.nyu.edu/about/policies-guidelines-compliance/policies-and-guidelines/faculty-handbook.html>, must be disclosed and assigned on a timely basis in accordance with the terms of that Statement of Policy as in effect from time to time.

(d) Competing with NYU.

(i) Engaging in activities that are in direct competition with NYU.

(ii) Holding, directly or indirectly, an ownership or other financial interest (such as a royalty interest) or having an Employment/Management/Fiduciary Role in an enterprise that is a competitor of NYU or promoting the interests of such enterprise at NYU. Holding, directly or indirectly, an Ownership Interest will not, by itself, be deemed to be a Conflict of Interest where: the interest is in an enterprise held through a diversified investment vehicle (such as a broad-based mutual fund or exchange traded fund) in which neither the faculty member or Investigator, or his or her Immediate Family Members, collectively, has a 15% or greater direct or indirect interest; or where the interest is held in publicly-traded securities in which neither the faculty member or Investigator, or his or her Immediate Family Members, collectively, holds directly or indirectly securities valued in excess of \$5,000 or that represent more than a 5% interest of any class of a company's stock or shares;

(e) Business Arrangements for Personal Benefit. Participating, directly or indirectly, in the selection, award or administration (including attempting to influence the purchase of products or services as through a recommendation or involvement in the subsequent performance of the business arrangement) of any business arrangement involving NYU and an enterprise in which the faculty member or Investigator holds, directly or indirectly, an ownership or other financial interest (such as a royalty interest) or has an Employment/Management/Fiduciary Role.

(f) Gifts Intending to Influence. Accepting gifts (including entertainment), a loan (other than an arm's length loan made in the ordinary course of business from a banking or other financial institution) or a favor of more than nominal value from any person or entity with a business relationship, or seeking to have a business relationship with, NYU or its faculty, employees, students, alumni or patients if the offer or acceptance of the gift could reasonably be viewed as intended to influence the business relationship.

(g) Failure to strictly comply with NYU policies and other rules, regulations and standards of conduct.

Examples of specific Conflicts of Interest intended to illustrate certain of the principles described in this Section IV.C. are set forth in Exhibit A to this policy.

#### D. Circumstances Under Which Conflicts of Interest May Be Permitted

It is recognized that certain Conflicts of Interest may arise in situations in which a faculty member or Investigator does not know or have reason to know of the conflict. In such situations the person should disclose the Conflict of Interest immediately upon learning of it. While Conflicts of Interest must be disclosed, they normally will be permitted where they are a minor, but an inseparable, part of a larger business relationship, or as a practical matter cannot realistically be eliminated, provided they are highly unlikely to pose a significant Conflict of Interest and the faculty member or Investigator is

not in a position to influence NYU in its decision-making regarding the transaction or to benefit from NYU's transaction with the outside entity.

In considering whether a Conflict of Interest arising from a faculty member's or an Investigator's Outside Activities may be permitted, favorable factors include:

- (a) The faculty member or Investigator fully disclosing in advance to NYU the material facts of the proposed Outside Activity, including the specific financial interest(s) and/or role(s) the faculty member or Investigator proposes to undertake;
- (b) The faculty member or Investigator refraining from voting or exercising any personal influence whatsoever in connection with the selection, award or administration of any matter that gives rise to a Conflict of Interest;
- (c) The faculty member or Investigator otherwise avoiding participating in any dealings between NYU, or its faculty, employees, students, alumni or patients, and the person, entity or company with whom or in which the faculty member or Investigator (or Immediate Family Member) has a financial interest or an Employment/Management/Fiduciary Role, including with respect to the selection of such person, entity or company as a vendor or business partner of NYU (or as a supplier of goods or services to NYU faculty, employees, students, alumni or patients) or the subsequent award or administration;
- (d) The Outside Activities are conducted on an arm's length basis at fair market value; and
- (e) NYU determines in accordance with Section V of this policy that the Conflict of Interest is not inconsistent with the best interests of NYU.

Where a Conflict of Interest arising from a faculty member's or Investigator's Outside Activities is permitted, the permission may be conditioned on adherence to a specified management plan.

#### E. Training

All NYU faculty members and Investigators need to be familiar with this policy and may be required by their School Dean or the Provost (the Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing) to complete training regarding this policy and their responsibilities regarding activities that may constitute a Conflict of Interest.

### **V. PROCEDURES: DISCLOSURES, REVIEW AND RESPONSIBILITIES**

The responsibility in the first instance for determining whether an activity presents a Conflict of Commitment or Conflict of Interest rests with the faculty member or Investigator concerned. If there is any reasonable doubt as to whether an activity may constitute such a conflict, or there is a question about whether an activity is permitted under this policy, the faculty member or Investigator must disclose the actual, potential or appearance of conflict to and seek guidance from his or her department chair or School Dean, or the office of the Provost (the Executive Vice President for Health in the case of the Schools of Medicine, Dentistry, and Nursing) or the Office of the General Counsel.

Conflicts must be disclosed in writing; and any waiver of the conflict or management plan must be reduced to writing.

#### A. Disclosures

##### (1) Faculty and Other Investigators: Annual Disclosures

On an annual basis, all full-time faculty, persons identified by the Office of the Provost as Investigators (through processes it determines) and others as requested by a School Dean or the Office of the Provost must complete and submit to their School Dean the applicable annual disclosure form then in effect, which form will refer faculty and Investigators and, where applicable, others to this policy and any related policies of the applicable School (including the availability of this policy and any applicable School policy on the NYU website). Such annual disclosure form requires, among other matters: (a) certification of compliance with this policy and related policies of the applicable School; (b) disclosure of information about the faculty member's or Investigator's or other's (and his or her Immediate Family Members) Outside Activities and other personal, professional, financial, ownership or other interests (including Ownership Interests and Remuneration) that could reasonably be relevant to assessing whether there might be a Conflict of Interest as described in Section IV of this policy and in the Addendum for Conflicts of Interest in Research and Other Sponsored Projects; and (c) in the case of faculty, disclosure of information pertinent to a Conflict of Commitment as described in Section III of this policy. Unless required under the implementation of this Policy by the faculty member's School, disclosures of uncompensated scholarly and professional activities performed in connection with a faculty member's appointment to NYU, such as lectures or seminars sponsored by governmental or non-profit entities, service on advisory committees or review panels for government or non-profit entities, including professional associations, and services on the editorial board of a journal in the field of the faculty member's appointment, will not be required in the annual disclosure form.

Such disclosures will be reviewed according to procedures described in Section V.B below.

##### (2) Faculty and Other Investigators: Research and Other Sponsored Projects: Reporting Requirements

Each time a faculty member or other Investigator is planning to participate in proposed Research and Other Sponsored Projects, the faculty member and each other Investigator involved with the proposed Research and Other Sponsored Projects must make the disclosures required by Section IV.A of the Addendum on Conflicts of Interest in Research and Other Sponsored Projects.

##### (3) Faculty and Other Investigators: Ad Hoc Disclosures

Faculty members and Investigators have a duty to disclose to the School Dean on an ad hoc basis current, proposed or pending situations that may raise questions of Conflict of Commitment or Conflict of Interest, in advance of the conflict arising if possible, and otherwise as soon as such situations become known to the faculty member or Investigator. Each time a faculty member or Investigator proposes to engage in a transaction (e.g., gift, technology licensing arrangement, purchase, etc.) with a person or entity as to which the faculty member or Investigator would have a Conflict of Interest as described in Section IV of this policy, the faculty member or Investigator must disclose the matter to the School Dean on an ad hoc basis.

NYU may require a faculty member or Investigator to complete an ad hoc conflict disclosure form at any time.

Such disclosures will be reviewed according to procedures described in Section V.B below.

Conflicts must be disclosed in writing; and any waiver of the conflict or management plan must be reduced to writing.

## B. Review Procedures

### (1) Review of Annual and Ad Hoc Disclosures

Annual disclosures and ad-hoc disclosures will be reviewed by the School Dean in accordance with the procedures approved for the School by the Provost (the Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing). Such procedures may provide that the School Dean forward any disclosure that presents a Conflict of Interest or a Conflict of Commitment to a Faculty Advisory Committee on Conflict of Interest and Conflict of Commitment, as described in Section V.C. below (a “Committee”). For any matter referred to it, the Committee will make a recommendation to the School Dean and/or the Provost (the Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing) regarding the existence and extent of a Conflict of Interest and, as appropriate, a proposed resolution to manage or eliminate any Conflict. See Section IV.B. above regarding the management of Conflicts of Interest. Conflicts must be disclosed in writing; and any waiver of the conflict or management plan must be reduced to writing.

### (2) Review of Research and Other Sponsored Projects Disclosures

Disclosures associated with Research and Other Sponsored Projects will be reviewed in accordance with Section IV.B of the Addendum on Conflicts of Interest in Research and Other Sponsored Projects. Conflicts must be disclosed in writing; and any waiver of the conflict or management plan must be reduced to writing.

## C. Responsibilities

### (1) Faculty Advisory Committees on Conflict of Interest and Conflict of Commitment

The Provost may establish a Faculty Advisory Committee on Conflict of Interest and Conflict of Commitment when the Provost believes it would be useful to do so; a School Dean or the Senior Vice Provost for Research (the EVP for Health with respect to the Schools of Dentistry and Nursing) may ask the Provost to establish such a Committee when the person believes such a Committee would be useful. The task of such a Committee may include reviewing all referrals of identified Conflict of Interest or Conflict of Commitment that have been referred by School Deans or another source in accordance with this policy. A Committee’s role is advisory to the School Deans and to the Senior Vice Provost for Research, except in the Schools of Dentistry and Nursing, where the Committee’s role is advisory to the School Dean and the Executive Vice President for Health.

In addition to the Committees contemplated by this policy, each School Dean may establish separate conflict of interest committee(s), which may be faculty/Investigator advisory committees, to review other conflicts under the policies of the relevant School.

(2) Responsibility of the Senior Vice Provost for Research

The Provost has designated the Senior Vice Provost for Research as the Provost's representative for managing this policy and its implementation at Schools other than the Schools of Medicine, Dentistry and Nursing. The Senior Vice Provost for Research will resolve any disagreements between a School Dean and the appropriate Committee.

(3) Responsibility of the Executive Vice President for Health

The Provost has designated the Executive Vice President for Health as the representative for managing this policy and its implementation for the Schools of Medicine, Dentistry and Nursing. The Executive Vice President for Health will resolve any disagreements between a School Dean and the appropriate Committee.

(4) Responsibility of the School Deans (other than the Dean of the School of Medicine)

The School Deans are responsible for establishing procedures to implement this policy, to provide any mandatory training, and to ensure timely collection and review of their faculty's and Investigators' annual and ad hoc disclosures. School Deans will refer disclosures of actual, potential or appearance of conflicts in accordance with the procedures of the School approved by the Provost (the Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing) and work, if necessary, with an applicable Committee or the Senior Vice Provost for Research (Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing), to ensure that all conflicts are eliminated or managed.

Each School Dean will provide a report annually to the Provost (and also to the Executive Vice President for Health in the case of the Schools of Dentistry and Nursing) on their School's compliance with this policy. Such report will include the number of annual disclosures required to be filed by the faculty and other Investigators of that School, the number received and reviewed, and the outcome of the reviews; the number of disclosures reporting Conflicts of Interest and Conflicts of Commitment, and the outcome of those reviews; and other information requested by the Provost (Executive Vice President for Health in the case of the Schools of Dentistry and Nursing).

(5) Responsibility of the Dean of the School of Medicine

In recognition of the unique significance of conflicts at an integrated academic medical center, the Provost and Executive Vice President for Health have delegated broad authority to the Dean of the School of Medicine to interpret the principles outlined in this policy for implementation in connection with all matters under this policy arising out of the School of Medicine. As is the case for all NYU policies, the Dean of the School of Medicine may introduce additional restrictions to this policy in order to implement the principles outlined above.

The Dean of the School of Medicine will provide a report annually to the Provost and the Executive Vice President for Health on the School of Medicine's compliance with this policy. Such report will include the number of annual disclosures required to be filed by the faculty and other Investigators of the School of Medicine, the number received and reviewed, and the outcome of the reviews; the

number of disclosures reporting Conflicts of Interest and Conflicts of Commitment, and the outcome of those reviews; and other information requested by the Executive Vice President for Health.

#### D. Appeals

Should a faculty member or an Investigator or other person a School Dean or the Office of the Provost has made subject to this policy wish to appeal a decision made by a School Dean on any matter contemplated by this policy, the faculty member or Investigator or other person may present the appeal to the Provost (the Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing), who will consider the case in consultation with the School Dean and, at his or her discretion, an appropriate Committee as contemplated by this policy.

#### E. Enforcement

Violations of this policy are subject to disciplinary action, up to and including termination of employment or association with NYU, in accordance with the NYU disciplinary policies and procedures applicable to the respective faculty member or Investigator as set forth in the Faculty Handbook and/or the applicable NYU rules for the category of person involved, including in the applicable policies and procedures of the relevant Schools.

For matters related to Research and Other Sponsored Projects, additional enforcement provisions are set forth in Section IV.E. of the Addendum on Conflicts of Interest in Research and Other Sponsored Projects.

#### F. Record Retention

Records related to this policy will be maintained in accordance with NYU's Retention and Destruction of Records Policy as in effect from time to time. For matters related to Research and Other Sponsored Projects, additional record retention requirements are set forth in Section IV.F. of the Addendum on Conflicts of Interest in Research and Other Sponsored Projects.

### Examples of Conflict of Interest

The following are examples of specific Conflicts of Interest intended to illustrate certain of the principles described in Section IV above: Additional examples of Conflicts of Interest are set forth in Section V. of the Addendum on Conflicts of Interest in Research and Other Sponsored Projects.

- (1) A faculty member or Investigator proposes to take a Consulting position to assist an organization that seeks to compete directly with an NYU program. For example, a faculty member in the School of Medicine proposes to take a Consulting position with a major academic medical center in NYC in a clinical area that competes directly with NYU or a faculty member proposes to take a Consulting position to assist a major university in its efforts to establish a campus that would compete with one of NYU's comprehensive campuses.
- (2) A faculty member or Investigator accepts a payment from a company with which the faculty member or Investigator recommends NYU contract.
- (3) A faculty member or Investigator proposes that NYU enter into a business transaction with an entity in which the faculty member or Investigator (or his or her Immediate Family Member) has an Ownership Interest.
- (4) A faculty member or Investigator proposes that NYU use or purchase a product, which would result in an economic benefit to the faculty member or Investigator or an Immediate Family. For example, a faculty member advocates the use of software the faculty member created prior to joining NYU and as to which the faculty member receives a royalty based on the commercial use of the software.
- (5) A faculty member or Investigator proposes to accept a gift (which includes entertainment) from an entity that is seeking to sell a product to NYU and as to which the faculty member's or Investigator's view of the product may be solicited before a purchasing decision is made by NYU.
- (6) A faculty member or Investigator proposes that NYU enter into a technology licensing arrangement with an entity in which the faculty member or Investigator or an Immediate Family Member serves on the board of directors or is employed.
- (7) A faculty member or Investigator proposes that NYU hire or contract with a member of his or her family for a position that is within his or her direct or indirect supervision or control. NYU's employment of a family member must be in accordance with NYU's *Policy on the Employment of Members of the Same Family*.
- (8) A faculty member or Investigator proposes to undertake or orient his or her research at NYU to serve the private interests of an outside firm without disclosure and permission.
- (9) A faculty member or Investigator proposes to share unpublished data from NYU research with a company as part of a consulting engagement or in discussions about a proposed consulting engagement.

(10) A student is a principal in a company and offers his or her professor compensated work with that company, or offers to engage the professor after the course is completed.

(11) A faculty member or Investigator proposes that NYU offer its employees or alumni an insurance policy with a company in which the faculty member or Investigator or an Immediate Family Member serves on the board of directors.

## **Addendum on Conflicts of Interest in Research and Other Sponsored Projects**

This addendum supplements the Policy on Academic Conflict of Interest and Conflict of Commitment (referred to in this Addendum as the “policy”) with respect to Conflicts of Interest in Research and Other Sponsored Projects. It is intended, without reference to the other provisions of the policy or other NYU policies, to meet NYU’s obligations to maintain a policy on financial conflicts of interest in research funded by federal sponsoring agencies (including the Public Health Service of the U.S. Department of Health and Human Services and the National Science Foundation).

This addendum applies to all Investigators of Research and Other Sponsored Projects, where “Research and Other Sponsored Projects” means research projects conducted at or under the auspices of NYU, whether or not externally funded, and externally-funded training or professional service projects conducted at or under the auspices of NYU, and “Investigator” means the principal investigators or program directors, and any other persons, regardless of title or position, who are responsible for the design, conduct or reporting of such projects, or who propose funding for such projects including both members of the University Community and persons doing the foregoing for subgrantees, contractors, collaborators, or consultants. Most but not all Investigators are NYU faculty members. The principles set forth herein also may serve to provide guidance in analogous non-research situations.

### **I. GENERAL PRINCIPLES**

NYU has a strong commitment to the principle of open and objective inquiry in the conduct of its research. Investigators participating in research at NYU have a primary obligation to conduct the research free of a Conflict of Interest so as to avoid the tainting or the perception of tainting of the research.

Individual Schools may wish to supplement this addendum with policies applicable to their Investigators. To ensure consistency with NYU policies, such School policies must be approved by the Provost (the Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing).

### **II. DEFINITIONS**

References in this addendum to the policy refer to the Policy on Academic Conflict of Interest and Conflict of Commitment.

For purposes of this addendum, terms have the meaning as set forth in the policy unless separately defined in this addendum.

A **Conflict of Interest**, as discussed in greater detail in the policy, means any circumstance in which the personal, professional, financial or other interests of an individual (including the Immediate Family Members of the individual) may potentially or actually diverge from, or may be reasonably perceived as potentially or actually diverging from, his or her professional obligations to NYU and the interests of NYU. A Conflict of Interest may exist whenever an independent observer might reasonably question whether the individual's professional actions or decisions, including the ethical and objective

conduct of scholarship, research or clinical care, are determined by considerations of personal gain, financial or otherwise.

**Employment/Management/Fiduciary Role** means a position involving service, in either a personal or representative capacity, as an employee, executive, manager, officer, director, trustee, or equivalent in a business, enterprise or entity other than NYU or an entity that is 50% or more owned or controlled by NYU.

**FCOI** or Financial Conflict of Interest means a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of a specific Research and Other Sponsored Projects. An FCOI is a Conflict of Interest under the policy.

**Immediate Family Members** include an individual's spouse or domestic partner or person in a civil union or similar relationship, dependent children, and any other family members residing in the same household.

**Institutional Responsibilities** means an Investigator's professional responsibilities on behalf of NYU, including research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as institutional review boards or data and safety monitoring boards.

**Principal Investigator, Project Director or Program Director** is the person with **primary** responsibility for the design, conduct, or reporting of Research and Other Sponsored Projects and for identifying other Investigators on their specific research project at or under the auspices of NYU. All Principal Investigators are NYU faculty members or NYU employees who have been granted an exception under NYU Code 103 Policy Addendum at the Washington Square campus. All Principal Investigators are Investigators.

**Investigator** means any person, including the Principal Investigator, regardless of title or position, who is responsible for the design, conduct or reporting of Research and Other Sponsored Projects. Most, but not all, Investigators are NYU faculty members.

For purposes of this addendum, Investigator also includes outside persons who are responsible for doing any of the foregoing for subgrantees, contractors, collaborators or consultants of NYU Research and Other Sponsored Projects as determined by the applicable School in consultation with the applicable principal investigator or program director. Section III of this addendum outlines the circumstances under which such external Investigators will be required to comply with the pertinent portions of this addendum. Most, but not all, Investigators are NYU faculty members.

**NYU** includes the Schools and other units of NYU, NYU's Global Network University sites, and all University Affiliates (as each term is defined in NYU's Developing University Policies, as amended from time to time).

**Non-PHS Research and Other Sponsored Projects** means any Research and Other Sponsored Projects that is not funded or proposed to be funded by PHS through any of its organizational units. Non-PHS Research and Other Sponsored Projects will become PHS Research and Other Sponsored Projects if, at any time, PHS funding is obtained or proposed.

**Outside Activities** include any external, remunerated consulting involving an individual's professional competence or other business activities and external professional and academic endeavors, such as public service or *pro bono* work, performed outside of the faculty member's appointment to NYU or an Investigator's employment or association with NYU.

**Ownership Interest** means holding a financial or ownership interest in a business or entity, including stock, stock option, warrant, convertible debt, partnership interest, LLP/LLC interest, or other ownership interest or right to obtain an ownership interest. The value of an Ownership Interest is determined through reference to public prices or other reasonable measures of fair market value where public prices are not available.

**PHS** means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

**PHS-Funded Research and Other Sponsored Projects** means any Research and Other Sponsored Projects funded (or proposed to be funded) in whole or in part by PHS through any of its organizational units. PHS-Funded Research and Other Sponsored Projects are subject to the PHS Regulations.

**PHS Regulations** means the regulations issued by the U.S. Department of Health and Human Services (HHS) entitled "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought," (see: <http://grants.nih.gov/grants/policy/coi/>), as the same may be amended from time to time.

**Reimbursed or Sponsored Travel (applies ONLY to PHS –Funded Research and Other Sponsored Projects and for Non-PHS-Funded Research and Other Sponsored Projects that incorporate the PHS regulations)** means any reimbursed or sponsored travel (i.e. that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to institutional responsibilities, when aggregated with other financial interests per entity exceeds \$5,000 in the 12 months prior to disclosure. Excludes travel reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education.

**Remuneration** includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid editorial or authorship activities). Income for scholarly and professional activities performed in connection with a faculty member's appointment to NYU from seminars, lectures, teaching engagements or service on advisory committees or review panels sponsored by a federal, state, or local government agency, or an institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education, for scholarly and professional activities performed in connection with a faculty member's appointment to NYU, such as lectures or seminars, editorial or authorship activities, service on advisory committees or review panels (including professional associations), are **excluded** from the definition of Remuneration.

**Research and Other Sponsored Projects** means any research project conducted at or under the auspices of NYU, whether or not externally funded, and any externally-funded training or professional service project conducted at or under the auspices of NYU. Research and Other Sponsored Projects includes any systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge, including basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test, drug or device), and non-research projects such as training, clinical services, educational conferences, exhibitions, performances, archives, workshops, and library projects for which external funding is received. Research and Other Sponsored Projects includes any such activity for which funding is available from external sources through a grant, contract or agreement, including, but not limited to, research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects and research resources awards.

**Royalty Income** means any royalty income, licensing income or other proceeds (e.g., payments linked to product sales or other usage and milestone payments), or the written contractual right to receive future royalties, licensing income or other proceeds, directly or indirectly, under a pending or issued patent, license, copyright or other property right, and includes, for purpose of this policy, all income received by the person from NYU in accordance with NYU's intellectual property policies, including its *Statement of Policy on Patents*.

**School** means each NYU school, college and institute that functions similarly to a school or college (such as IFA, ISAW, Courant, CUSP, and the SoE), each NYU comprehensive campus (such as New York, Abu Dhabi, **Shanghai**) and also may include for purposes of this policy other global sites as designated by the Provost.

**School Dean** means the dean, or his or her designee, of each NYU school and college, the director or each NYU institute that functions similarly to a school or college (such as IFA, ISAW, Courant and CUSP) and the Vice Chancellor of each NYU comprehensive campus (such as New York and Abu Dhabi). In the case of other NYU global sites that have faculty and/or Investigators, the Provost may designate someone to fulfill some or all of the duties of a School Dean as described herein with respect to such global sites.

**Significant Financial Interest** has a different meaning for PHS Research and Other Sponsored Projects and for Non-PHS-Funded Research and Other Sponsored Projects that incorporate the PHS Regulations into the funding award terms than it has for other Non-PHS-Funded Research and Other Sponsored Projects.

A. Research and Other Sponsored Projects that incorporate the PHS Regulations

For PHS-Funded Research and Other Sponsored Projects and for Non-PHS-Funded Research and Other Sponsored Projects that incorporate the PHS Regulations into the funding award terms, Significant Financial Interest means any financial interest consisting of one or more of the following interests of an Investigator (which also includes those of the Investigator's Immediate Family Members) that reasonably appears to be related to the Investigator's Institutional Responsibilities with NYU:

(1) With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any Remuneration and estimated travel reimbursement and travel paid from Outside Activities received from the entity in the twelve months preceding the disclosure and the value of any Ownership Interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000; or

(2) With regard to any non-publicly traded entity, a Significant Financial Interest exists if (i) the value of Remuneration and estimated travel reimbursement and travel paid from Outside Activities received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or (ii) there is any Ownership Interest in the entity; or

(3) Intellectual property rights (e.g., patents or copyrights), royalties from such rights and agreements to share in royalties related to such rights, upon receipt of the Royalty Income related to such rights and interests.

B. Non-PHS Research and Other Sponsored Projects that do not incorporate the PHS Regulations

For Non-PHS Research and Other Sponsored Projects that do not incorporate the PHS Regulations, Significant Financial Interest means a financial interest consisting of one of more of the following interests of an Investigator (which also includes those of the Investigator's Immediate Family Members) in an entity other than NYU that could reasonably appear to be affected by, or might in turn affect, the Non-PHS Research and Other Sponsored Projects:

(1) With regard to any publicly traded entity, the value of any Remuneration from Outside Activities received from the entity in the twelve months preceding the disclosure and the value of any Ownership Interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000, or (ii) the Ownership Interest as of the date of disclosure exceeds five percent (5%) in any class of the entity's securities; or

(2) With regard to any non-publicly traded entity, (i) the value of Remuneration from Outside Activities received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or (ii) there is any Ownership Interest in the entity; or

(3) Intellectual property rights (e.g., patents or copyrights), royalties from such rights, and agreements to share in royalties related to such rights; or

C. Both PHS-Funded Research and Other Sponsored Projects and Non-PHS-Funded Research and Other Sponsored Projects

For both PHS-Funded Research and Other Sponsored Projects and Non-PHS-Funded Research and Other Sponsored Projects, the following types of financial interests are excluded from the definition of Significant Financial Interest:

(1) Salary, royalties, or other remuneration paid by NYU while the recipient is currently employed or otherwise appointed by NYU;

(2) Income from diversified investment vehicles, such as broad-based mutual funds and exchange traded funds, as long as the Investigator, or his or her Immediate Family members, collectively, do

not have a 15% or greater direct or indirect interest in the vehicle and do not have an Employment/Management/Fiduciary Role in the vehicle;

(3) Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education;

(4) Income from service on advisory committees or review panels for a federal, state, or local government agency, or an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education; and

(5) Interests in and Remuneration from a publicly traded entity where the total aggregate value of (a) Remuneration received from the entity in the twelve months preceding the disclosure and (b) Ownership Interest in the entity as of the date of disclosure is less than \$5,000, provided that the Ownership Interest also is less than five percent (5%) in any class of the entity's securities.

### **III. POLICY AND DISCUSSION**

As with all Conflicts of Interest, NYU has broad power to require disclosures of FCOI arising out of Research and Other Sponsored Projects to determine whether a FCOI exists, to investigate FCOI, to manage or eliminate FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias, to impose appropriate sanctions on Investigators who violate this addendum, to release information about FCOI and to require Investigators to take FCOI training. By way of example, the types of management actions that NYU may take in response to a FCOI arising out of a Research and Other Sponsored Projects include: reviewing and, where appropriate, monitoring the conflict; imposing conditions or restrictions intended to manage, reduce or eliminate such conflict; requiring disclosure of the FCOI or of additional information (e.g., requiring disclosure of the FCOI when presenting or publishing the research or requiring disclosure of the FCOI to participants in a human subjects research project); obtaining background documents; prohibiting a conflicted person from involvement, including exercising personal influence, in connection with a matter; revising the design of Research and Other Sponsored Projects to address potential bias from the FCOI; obtaining waivers, consents and/or authorizations; appointing an oversight body to monitor the FOCI and/or other activities (e.g., a body to monitor and review ongoing Research and Other Sponsored Projects or other activities); and requiring relinquishment of interests and/or restructuring or severance of relationships that contribute to the FCOI. In addition, NYU can eliminate the FCOI, as for example by prohibiting an Investigator from participating in Research and Other Sponsored Projects or by requiring action that eliminates the FCOI as a condition of participating in an activity (e.g., divestment of an Ownership Interest giving rise to a FCOI).

While every FCOI is subject to prior disclosure, review, approval and adherence to any required management plan, in the case of Research and Other Sponsored Projects, there are very specific procedures with respect to the advance disclosure and review of FCOIs by all Investigators as set forth in Section IV of this addendum. In each case, a determination will be made as to whether the proposed activity can proceed as contemplated, whether it can proceed only if a management plan is adhered to, or whether the FCOI is so significant that it must be eliminated.

Human subjects research of greater than minimal risk is the most sensitive area of research. Accordingly, the disclosures and review in this area, addressed in Section IV of this addendum, include additional requirements and determinations as to whether to proceed and under what conditions are held to an even higher standard.

This addendum applies to all research conducted at or under the auspices of NYU, whether or not funded by a federal sponsoring agency or another external funding source. Research and Other Sponsored Projects that are sponsored often are subject to additional conflict rules, including those imposed by a federal sponsoring agency and those imposed contractually by private funding sources and collaborators. It is the policy of NYU to comply with all such requirements. This addendum is believed to be in compliance with the applicable federal sponsoring agency requirements; to the extent there is any issue about whether this addendum wholly complies with a sponsoring agency or other sponsor requirement, it is to be interpreted to assure compliance. Additionally, Research and Other Sponsored Projects must be conducted in accordance with all NYU policies, including the policy and policies of the relevant School. Each Investigator is responsible for assuring his or her compliance with the requirements applicable to the Investigator's specific Research and Other Sponsored Projects.

In instances where NYU carries out funded Research and Other Sponsored Projects through subgrantees, subcontractors, or collaborators, NYU will, to the extent it is required to under the grant or contract terms with the funder, either require, by written agreement, such external Investigators to comply with the pertinent portions of this addendum, or require, by written agreement, the entities for which the Investigators work to provide assurances that such entities have a written conflicts policy in effect that applies to their Investigators and complies with applicable federal sponsoring agency requirements. Such written agreements will specify the time period(s) for the subgrantees, subcontractors or collaborators to report to NYU all identified FCOI or to submit to NYU all Investigator disclosures of significant financial interests, in each case so as to enable NYU to meet its obligations under this addendum, and its obligations to external sponsors, if applicable.

Examples of specific FCOI intended to illustrate certain of the principles described in this Section III are set forth in Section V of this addendum.

All Investigators involved in Research and Other Sponsored Projects may be required by the funding source to periodically complete an appropriate training program prior to engaging in Research and Other Sponsored Projects. Each Investigator involved in PHS-Funded Research and Other Sponsored Projects must complete training regarding this policy and the PHS Regulations, and the Investigator's responsibilities regarding disclosure of Significant Financial Interest as required under this policy, prior to first engaging in PHS-Funded Research and Other Sponsored Projects, at least every four years thereafter, and as otherwise may be requested by the Provost (the Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing) or his or her department chair or School Dean.

#### **IV. PROCEDURES: DISCLOSURES, REVIEW AND RESPONSIBILITIES**

The responsibility in the first instance for determining whether an activity presents a Conflict of Interest rests with the Investigator concerned. If there is any reasonable doubt as to whether an activity may constitute such a conflict, or there is a question about whether an activity is permitted under the policy, including this addendum, the Investigator should disclose the actual, potential or appearance of conflict to and seek guidance from his or her department chair or School Dean, the Office of the

Provost (the Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing) or the Office of the General Counsel.

## A. Disclosures

### (1) Investigator: Annual Disclosures

On an annual basis, Investigators who are members of the University Community must complete and submit the applicable annual disclosure form to the extent required by Section V.A.(1) of the policy. Each Investigator who is a member of the University Community and who is involved in PHS-Funded Research and Other Sponsored Projects must complete an annual disclosure form in the year prior to each submission of a proposed PHS-Funded Research and Other Sponsored Projects or complete an annual disclosure form prior to the next submission of a proposed PHS-Funded Research and Other Sponsored Projects.

### (2) Research and Other Sponsored Projects: Reporting Requirements

Each time an Investigator is planning to participate in proposed Research and Other Sponsored Projects, the Investigators involved with the proposed Research and Other Sponsored Projects must submit the applicable Investigator financial interest disclosure form in effect, which form will refer the Investigator to the policy, including this addendum (including their availability, on the NYU website). Such Investigator financial interest disclosure form requires, among other matters, disclosure of the Investigator's and his or her Immediate Family Members' (i) Significant Financial Interests (specifying, in the event of a PHS-Funded Research and Other Sponsored Projects or a Non-PHS-Funded Research and Other Sponsored Projects that incorporate the PHS Regulations into the funding award terms, if any such Significant Financial Interest could reasonably be determined to affect the design, conduct, or reporting of the Research and Other Sponsored Projects and specifying for each disclosed travel reimbursement and travel paid at a minimum, the purpose of each trip, the identity of each sponsor/organizer, its destination, and its duration); (ii) Employment/Management/Fiduciary Roles held in an entity whose financial interest could affect the Research and Other Sponsored Projects; and (iii) any rights held in intellectual property covering products or processes being used in the Research and Other Sponsored Projects (including any right to royalty income from intellectual property assigned to NYU under NYU's intellectual property policies, including its Statement of Policy on Patents). Such disclosure must be made prior to the submission of an application for the Research and Other Sponsored Projects to the sponsor, updated annually for the duration of the Research and Other Sponsored Projects, and updated within thirty days of discovering or acquiring any such new activity or interest (e.g., through purchase, marriage or inheritance). The Investigator financial interest disclosure form and annual update form must be submitted even if there is no interest, position or rights to disclose.

Such disclosures will be reviewed according to procedures described in Section IV.B. of this addendum.

### (3) Human Subjects Research Disclosures

Studies involving human subjects of greater than minimal risk and requiring review by an institutional review board (IRB) raise the most sensitive issues. Studies involving pre-clinical research (i.e., studies reasonably anticipated to contribute to an FDA application for research involving human subjects

within the next 12 months) also raise sensitive issues. For that reason, the scientific objectivity of an Investigator may be reasonably questioned in those cases where the Investigator has *any* personal interests which could be affected by the research -- no matter what positions or dollar amounts are involved.

Accordingly, the disclosures required for studies involving human subjects of greater than minimal risk are the same as those required with Research and Other Sponsored Projects in Paragraph "2" above, except that the definition of Significant Financial Interest will not include any minimum dollar limitations.

All disclosures will be reviewed according to procedures described in Section IV.B of this addendum.

## B. Review Procedures

Disclosures associated with Research and Other Sponsored Projects that are required under this addendum, including annual and investigator disclosures, will be reviewed by the School Dean in accordance with the procedures approved for the School by the Provost (the Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing). The School Dean is responsible for determining whether any disclosed interest could be affected by, or is an entity whose financial interest could be affected by, the specific Research and Other Sponsored Projects, and, if so related, whether the interest is an FCOI.

Whenever the School Dean identifies any FCOI in a Research and Other Sponsored Projects, the School Dean will refer such matter to the appropriate committee, unless the procedures approved for the School do not require such referral or the Provost (the Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing) agrees such referral is unnecessary. In the review, the School Dean and/or the appropriate committee will determine whether and the extent to which a FCOI exists and, as appropriate, a proposed resolution to manage or eliminate any FCOI. Management of an identified FCOI requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report as outlined below. See Section III of this addendum regarding the management of FCOI.

Where a FCOI is present but was not disclosed or reviewed in a timely manner, the School Dean and/or the appropriate committee will implement, on at least an interim basis, a conflicts mitigation plan that will include a review and determination as to whether the Research and Other Sponsored Projects, or any portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such Research and Other Sponsored Projects. Review and implementation of such conflicts mitigation plan must be completed in a timely manner. For PHS-Funded Research and Other Sponsored Projects, such review and implementation is required within sixty days of identifying the failure to disclose or review the FCOI.

For all matters referred to it, the appropriate committee will convey its decision to the School Dean, who will either accept it or refer it to the Provost (the Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing) for resolution.

The results of the review and any resulting conflict management and/or mitigation plan will be communicated to the principal investigator and to the Investigator(s) with the identified conflict (if

different), each of whom will need to agree to the plan(s) before the Research and Other Sponsored Projects may proceed.

For FCOI cases involving human subjects research, the approved conflict management and/or mitigation plan also will be communicated to the relevant IRB for further action. If the conflict management and/or mitigation plan permits the research to proceed with the conflicted Investigator, such plan will provide, at a minimum, for appropriate disclosure to human subjects involved in the research study, if any, and to the public in presentations and publications of resulting research data.

Commencement of a Research and Other Sponsored Projects (including any enrollment of research subjects) or expenditure of any awarded funds for the Research and Other Sponsored Projects may not occur until after completion of the review and evaluation of an Investigator's disclosure associated with the Research and Other Sponsored Projects, including the implementation of any necessary or appropriate management and/or mitigation plan and any reporting required to or by the sponsor prior to commencement relating to an Investigator's disclosure. In the case of an on-going Research and Other Sponsored Project, when a new Investigator discloses a Significant Financial Interest or an existing Investigator discloses a new Significant Financial Interest, the disclosure will be renewed in accordance with the procedures set forth in this Section IV.B(2), with the review and evaluation completed within sixty days, including implementation on an at least an interim basis of any necessary or appropriate management and/or mitigation plan, and with timely compliance with reporting required to or by the sponsor.

### C. Responsibilities

#### (1) Faculty Advisory Committees on Conflict of Interest and Conflict of Commitment

The Provost may establish a Faculty Advisory Committee on Conflict of Interest and Conflict of Commitment when the Provost believes it would be useful to do so; a School Dean or the Senior Vice Provost for Research (the EVP for Health with respect to the Schools of Dentistry and Nursing) may ask the Provost to establish such a committee when the person believes such a committee would be useful. The task for such a committee may include reviewing all referrals of identified Conflict of Interest that have been referred by School Deans or another source in accordance with this addendum. A committee's role is advisory to the School Deans and to the Senior Vice Provost for Research, except in the Schools of Dentistry and Nursing, where a committee's role is advisory to the School Dean and the Executive Vice President for Health.

The Dean of the School of Medicine has established a Faculty Advisory Research Conflict of Interest Committee at the School of Medicine whose task is to review all referrals of disclosures of identified FCOI arising out of Research and Other Sponsored Projects conducted at or under the auspices of the School of Medicine or arising out of research studies requiring review by the School of Medicine's IRB under NYU policies. The Committee's role is advisory to the Dean of the School of Medicine and Executive Vice President for Health.

In addition to the Committees contemplated by the policy, each School Dean may establish separate conflict of interest committee(s), which may be faculty/Investigator advisory committees, to review other conflicts under the policies of the relevant School.

(2) Responsibility of the Senior Vice Provost for Research

The Provost has designated the Senior Vice Provost for Research as the Provost's representative for managing this addendum and its implementation at Schools other than the Schools of Medicine, Dentistry and Nursing. The Senior Vice Provost for Research will resolve any disagreements between a School Dean and the appropriate Committee.

(3) Responsibility of the Executive Vice President for Health

The Provost has designated the Executive Vice President for Health as the representative for managing this addendum and its implementation for the Schools of Medicine, Dentistry and Nursing. The Executive Vice President for Health will resolve any disagreements between a School Dean and the appropriate Committee.

(4) Responsibility of the School Deans (other than the Dean of the School of Medicine)

The School Deans are responsible for establishing procedures to implement this addendum, to provide any mandatory training, and to ensure timely collection and review of their Investigators' Research and Other Sponsored Projects disclosures (including all research studies involving human subjects). School Deans will refer disclosures of potential, actual or perceived conflicts in accordance with the procedures of the School approved by the Provost (the Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing) and work, if necessary, with an applicable Committee or the Senior Vice Provost for Research (Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing), to ensure that all conflicts are eliminated or managed.

Each School Dean will provide a report annually to the Provost (and also to the Executive Vice President for Health in the case of the Schools of Dentistry and Nursing) on their School's compliance with this addendum. Such report will include the number of annual disclosures required to be filed by the Investigators of that School, the number received and reviewed, and the outcome of the reviews; the number of disclosures reporting FCOI, and the outcome of those reviews; and other information requested by the Provost (Executive Vice President for Health in the case of the Schools of Dentistry and Nursing).

(5) Responsibility of the Dean of the School of Medicine

In recognition of the unique significance of conflicts at an integrated academic medical center, the Provost and Executive Vice President for Health have delegated broad authority to the Dean of the School of Medicine to interpret the principles outlined in this addendum for implementation in connection with all matters under this addendum arising out of the School of Medicine and for all research studies involving human subject research reviewed by the School of Medicine's IRB. As is the case for all NYU policies, the Dean of the School of Medicine may introduce additional restrictions to this addendum in order to implement the principles outlined above.

The Dean of the School of Medicine will provide a report annually to the Provost and the Executive Vice President for Health on the School of Medicine's compliance with this addendum. Such report will include the number of annual disclosures required to be filed by the Investigators of the School of Medicine, the number received and reviewed, and the outcome of the reviews; the number of

disclosures reporting FCOI, and the outcome of those reviews; and other information requested by the Executive Vice President for Health.

#### D. Appeals

Should an Investigator wish to appeal a decision made by a School Dean on any matter contemplated by this addendum, the Investigator may present the appeal to the Provost (the Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing) who will consider the case in consultation with the School Dean and, at his or her discretion, the appropriate Committee contemplated by this addendum.

#### E. Enforcement

Violations of this addendum are considered violations of the policy and are subject to disciplinary action, up to and including termination of employment or association with NYU, in accordance with the NYU disciplinary policies and procedures applicable to the respective Investigator as set forth in the Faculty Handbook and/or the applicable NYU rules for the category of person involved, including in the applicable the policies and procedures of the relevant Schools.

For matters related to Research and Other Sponsored Projects, if there is a determination by the School Dean and/or the applicable Committee and/or Provost (the Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing) after review by the applicable Committee that the failure of an Investigator to comply with this addendum, including a conflict management or mitigation plan adopted pursuant to this addendum, has biased the design, conduct, or reporting of the Research and Other Sponsored Projects, the School Dean will promptly notify the Senior Vice Provost for Research (the Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing), who will coordinate notification of the project's sponsor and any other potentially affected party, require other notifications (e.g., to journals and sponsors of public presentations) as appropriate, and take appropriate other actions to maintain appropriate objectivity in the Research and Other Sponsored Projects.

In addition, in any case where such Research and Other Sponsored Projects' purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an Investigator with a FCOI that was not managed or reported to NYU as required, the School Dean, in consultation with the Senior Vice Provost for Research (the Executive Vice President for Health in the case of the Schools of Medicine, Dentistry and Nursing), will require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

#### F. Record Retention

Records related to this addendum will be maintained in accordance with NYU's Retention and Destruction of Records Policy as in effect from time to time; provided, however, that records relating to Investigator financial interest disclosures and NYU's review of, or response to, such disclosures (whether or not a disclosure resulted in a determination of a FCOI), will be maintained for at least three years from the date of submission of the final expenditures report (or such longer period as required by the federal sponsoring agency) on the applicable Research and Other Sponsored Projects even if a shorter retention period is specified under NYU's Retention and Destruction of Records

Policy. All records relating to Investigator financial interest disclosures and NYU's review of, or response to, such disclosures will be retained either by the appropriate Dean or by the Faculty Advisory Committee, as applicable.

## **V. EXAMPLES OF CONFLICT OF INTEREST**

The following are examples of specific Conflict of Interest arising out of a Research and Other Sponsored Projects intended to illustrate certain of the principles described in this addendum:

- (1) An Investigator proposes that NYU accept funding in support of his or her research from an entity in which the Investigator (or his or her Immediate Family Member) has an Employment/Management/Fiduciary Role.
- (2) An Investigator proposes that NYU accept research funding from an entity to assist in developing technologies owned by the entity where the Investigator engages in Consulting and receives Remuneration from the entity.
- (3) An Investigator proposes that NYU use or test a product made by an entity in which the Investigator (or his or her Immediate Family Member) has an Ownership Interest.
- (4) An Investigator proposes that NYU accept a Small Business Innovation Research (SBIR) program subcontract for research in the Investigator's laboratory from a "small business" start-up company founded by the Investigator and in which the Investigator has an Ownership Interest.
- (5) An Investigator proposes that NYU use or test in a clinical research study a product or process that is patented by NYU and as to which the Investigator receives Royalty Income pursuant to NYU's *Statement of Policy on Patents*.