

NYU LANGONE MEDICAL CENTER

POLICY ON CONFLICTS OF INTEREST IN RESEARCH AND SPONSORED PROGRAMS

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I. Applicability

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

II. General Policy

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

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

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

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

III. Disclosure

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

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

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

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

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

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

IV. Review and Evaluation

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

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

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

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

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

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

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

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

V. **Definitions**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

VI. Examples of Research Conflicts of Interest

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

VII. Enforcement

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

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

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

VIII. Administration

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

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

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

IX. Relationship to Other Policies

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

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