



Policy on Conflicts of Interest in Research and Other Sponsored Programs

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I. **Summary**

NYU Langone Health is committed to operating in an ethical manner and in compliance with applicable legal and regulatory requirements. Even the appearance of a significant conflict of interest in research at NYU Langone Health can be damaging to the reputation of NYU Langone Health.

NYU Langone Health's *Policies on Conflicts of Interest, Commitment and Consulting* provides a comprehensive approach for the identification, disclosure and oversight of all conflicts arising from the external interests and activities of NYU Langone Health and members of the NYU Langone Community, as well as the conduct of NYU Langone Health's business. The Policies require employed faculty members, designated employees, officers and trustees to disclose financial relationships for review on an annual basis. This Policy is a part of the *Policies* and requires disclosure of financial interests on a per project basis by individuals participating in research and sponsored programs at NYU Langone Health.

Under this Policy, individuals participating in research and other sponsored programs must disclose all financial interests that reasonably appear to be related to the individual's responsibilities at NYU Langone Health and to the specific project. NYU Langone Health, through its Conflicts of Interest Management Unit (CIMU), will then review and evaluate such disclosures, determine if a conflict of interest exists, and determine whether such conflict can be managed or must be eliminated in order to permit the researcher to engage in the project.

II. **Applicability**

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

III. **General Policy**

A. Investigators participating in a Sponsored Project conducted at or under the auspices of NYU Langone Health have a primary obligation to serve the purposes to which NYU Langone Health 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 NYU Langone Health’s designated officials reasonably determine that an Investigator’s Financial Interest could affect or be affected, or appear to affect or be affected, by the design, conduct or reporting of the Sponsored Project.

C. To assure that all potential Conflicts of Interest are identified, all Investigators participating in a Sponsored Project must submit disclosures of personal financial interests, of any value, of the Investigator and his or her Immediate Family that reasonably appear related to the Investigator’s Institutional Responsibilities with NYU Langone Health before and during the life of the Sponsored Project.

D. All potential Conflicts of Interest require disclosure, evaluation and either management or elimination under this Policy.

E. 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 Chief Scientific Officer of NYU Langone Health or the CIMU determine 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.

IV. **Disclosure**

Investigators must submit annual and project specific disclosures as described below. Disclosures must be completed and submitted even if no Financial Interests are disclosed. Disclosures of Financial Interests must be made in specific amounts. For PHS Sponsored Projects, disclosures of Paid/Reimbursed Travel must specify each instance of paid or reimbursed travel at a minimum, as well as the purpose of each trip, the identity of each sponsor/organizer, its destination and its duration.

A. Annual Disclosures. All Investigators who are part of the NYU Langone Community are required under NYU Langone Health’s *Policy on Conflicts of Interest in Business Affairs* to complete and submit an annual disclosure, which is reviewed in accordance with that Policy.

B. Project Disclosure – Upon Submission. Each Investigator planning to participate in a proposed Sponsored Project must complete and submit a research financial interest disclosure when prompted to following submission of the Sponsored Project to the Office of Science & Research (e.g., the Office of Sponsored Programs Administration (SPA) or the IRB). In the disclosure, Investigators must disclose all Financial Interests that reasonably relate to the Investigator’s Institutional Responsibilities with NYU Langone Health and to the specific Sponsored Project. The CIMU review and evaluation as described in Section V below.

C. Project Disclosure – Upon Annual Continuations. Each Investigator participating in a Sponsored Project must also complete and submit an investigator financial interest disclosure at each annual continuation of the Sponsored Project to the Office of Science & Research. Disclosures with Financial Interests will be subject to the review and evaluation process outlined in Section V.A(iv) below.

D. Project Disclosure – New Financial Interests. While a Sponsored Project is on-going, an Investigator must complete and submit an investigator financial interest disclosure to the Office of Science &

Research for 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 NYU Langone Health's *Policies on Conflicts of Interest, Commitment and Consulting*, and to meet NYU Langone Health's disclosure and/or reporting requirements under applicable laws, regulations, grants and/or contracts.

V. Review and Evaluation of Project Disclosures

A. Conflict of Interest Management Unit (CIMU) Review. The CIMU is responsible for the review of each disclosure of a Financial Interest to determine if it could give rise to a Conflict of Interest in the Sponsored Project, as described below.

- (i) **No Potential Conflict of Interest**. For disclosures of Financial Interests that the CIMU finds do not reasonably appear to give rise to a Conflict of Interest, the CIMU will advise the Office of Science & Research that there is no Conflict of Interest and no conflict management plan is required.
- (ii) **Potential Conflict of Interest without Significant Financial Interest**. For initial disclosures of a Financial Interest that is not a Significant Financial Interest, the CIMU will determine if a Conflict of Interest exists. If so, the Investigator's participation will generally be permitted, subject to an appropriate conflict management plan issued by the CIMU. Conflict management plans issued by the CIMU may be appealed to NYU Langone Health's Chief Scientific Officer. No expenditures may occur on the Sponsored Project until the CIMU's review and evaluation is complete and a conflict management plan is agreed to by both the principal investigator on the Sponsored Project and the Investigator with the disclosed Financial Interest, if a different individual.
- (iii) **Potential Conflict of Interest with Significant Financial Interest**. For initial disclosures of a Significant Financial Interest that could give rise to a Conflict of Interest, the CIMU will make a determination whether or not Compelling Circumstances exist to justify the Investigator's participation in the Sponsored Project notwithstanding the disclosed Significant Financial Interest.

For matters giving rise to a significant potential Conflict of Interest, the CIMU, in consultation with the Office of Legal Counsel and/or the Chief Scientific Officer, will first use diligent efforts to eliminate or manage the conflict. If the CIMU is unable to eliminate or manage the conflict or if recommended by the Chief Scientific Officer, the CIMU may refer the matter to the Business Conflict of Interest Committee (BCOIC).

If Compelling Circumstances are found, the CIMU will approve a conflict management plan as contemplated below. If Compelling Circumstances are not found or a conflict management plan is not approved or agreed to as provided in Section V.B below, the Conflict of Interest must be eliminated in order for the Investigator to be permitted to carry out the Sponsored Project. No expenditures may occur on the Sponsored Project until the CIMU's review and evaluation is complete and a conflict management plan is agreed to by both the principal investigator on the Sponsored Project and the Investigator with the disclosed Significant Financial Interest, if a different individual; or until the Conflict of Interest has been eliminated.

- (iv) **Previously Reviewed Disclosures**. For disclosures of a Financial Interest that has previously been reviewed and evaluated and is subject to a conflict management plan issued under this Policy, the CIMU may, in its discretion, approve the continuation of the conflict management plan. If the nature of the previously reviewed Financial Interest has changed or the amount materially increased,

however, the disclosed Financial Interest will be reviewed and evaluated by the CIMU 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.

B. Conflict Management Plan. If an Investigator's participation in a Sponsored Project is permitted notwithstanding a Conflict of Interest, the Investigator's participation must be subject to a conflict management plan issued by the CIMU. The purpose of the conflict management plan will be to foster transparency in related interests and relationships, maintain the objectivity of research design, conduct, and reporting, and best serve the rights and welfare of subjects enrolled in the research. Possible management strategies to be considered are listed in NYU Langone Health's *Procedures on Research Conflict of Interest and Sponsored Programs*. 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. In its review of Human Subjects Research projects, the IRB will consider the conflict management plans. The Sponsored Project cannot commence until IRB approval is released following receipt of the final determination and/or conflict management plan under this Policy. The principal investigator on the Sponsored Project and the Investigator with the managed Conflict of Interest must comply with all terms in the conflict management plan for the duration of the Sponsored Project. The CIMU is responsible for monitoring the compliance with the conflict management plan on an ongoing basis until the completion of the Sponsored Project.

C. Research Conflict of Interest Committee. Any matter under this Policy may be presented for review and evaluation by NYU Langone Health's Research Conflict of Interest Committee (RCOIC). The RCOIC's role is advisory to NYU Langone Health's Business Conflict of Interest Committee, the Chief Scientific Officer, and the CIMU.

D. Appeals to NYU Langone Health's Chief Scientific Officer. Determinations of the CIMU may be appealed to NYU Langone Health's Chief Scientific Officer. Appeals must be in writing and submitted to the CIMU. The CIMU will provide copies of the appeal to the Chief Scientific Officer. Decisions of the Chief Scientific Officer are final.

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

VI. Disclosure of Interests in Publications and Presentations

All Investigators must disclose their financial interests in publications and presentations whenever the Investigator has financial relationships with entities that could be perceived to influence, or that give the appearance of potentially influencing, what was included in the publication or presentation. Investigators with financial interests must adhere to any disclosure requirements in their conflict management plan and must comply with any disclosure requirements of the applicable journal or conference. If a disclosure requirement is not clear, Investigators should broadly disclose all applicable financial interests. Failure to make required disclosures or to comply with management plans is a violation of this Policy and will be cause for disciplinary action.

VII. Special PHS and Other Sponsor Requirements

A. Research Sponsors often impose additional rules about conflicts of interest as a condition of providing funding. It is the policy of NYU Langone Health to comply with all such requirements, including

the PHS Regulations which apply to all research funded by a PHS agency (i.e., NIH, AHRQ, CDC, FDA, HRSA, SAMHSA, OG, OASH, ASPR, ATSDR, and IHS). This Policy is believed to be in compliance with the applicable federal sponsoring agency requirements, including the PHS Regulations. To the extent there is any issue about whether or not this Policy wholly complies with a Sponsor requirement, it is to be interpreted to assure compliance. Each Investigator is responsible for assuring his or her compliance with the requirements applicable to the Investigator's specific Sponsored Project.

B. For Sponsored Projects subject to the PHS Regulations ("PHS Sponsored Projects"), in addition to the review and evaluation in Section V, the additional requirements outlined in NYU Langone Health's *Procedures on Conflicts of Interest in Research and Sponsored Programs covered by the PHS Regulations* apply. The additional requirements include the following:

- (i) A "PHS Conflict of Interest" exists when NYU Langone Health's designated official(s) reasonably determines that a PHS Significant Financial Interest (as defined in NYU Langone Health's *Procedures on Conflicts of Interest in Research and Sponsored Programs covered by the PHS Regulations*) could *directly and significantly* affect the design, conduct, or reporting of a PHS Sponsored Project.
- (ii) PHS Conflict of Interest Findings. The CIMU is responsible for determining if a disclosure of a PHS Significant Financial Interest in a PHS Sponsored Project has resulted in a PHS Conflict of Interest. If a PHS Conflict of Interest is determined to exist, it shall be managed and/or eliminated as a Conflict of Interest in accordance with Section V.
- (iii) Retrospective Reviews/ Mitigation Reports. If an initial or ongoing disclosure of a PHS Significant Financial Interest that could give rise to a PHS Conflict of Interest for the PHS Sponsored Project is not disclosed or reviewed in a timely manner, the CIMU will review and evaluate the disclosure. If the CIMU makes a PHS Conflict of Interest determination for a late disclosure or review, it will issue a conflict management plan within 60 days of the disclosure or review, as applicable. When non-compliance is found, the CIMU will conduct and document within 120 days of a determination of such non-compliance, a retrospective review of the Investigator's activities and the PHS Conflict of Interest. Examples of non-compliance include failure of an Investigator to disclose a PHS Significant Financial Interest that could give rise to a PHS Conflict of Interest in a timely manner; failure of NYU Langone Health to review and manage a PHS Significant Financial Interest determined to constitute a PHS Conflict of Interest in a timely manner; or failure of an Investigator to comply with the terms of a COI management plan relative to a PHS Conflict of Interest. This retrospective review will determine whether the PHS Sponsored Project, or any portion thereof conducted during the period of non-compliance, was biased in the design, conduct, or reporting of such PHS Sponsored Project. If a retrospective review results in a finding of bias, the CIMU must file a mitigation report with the PHS sponsor. Retrospective reviews and mitigation reports, if required, must be completed by the CIMU in a timely manner. In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a PHS Conflict of Interest that was not managed or reported as required by the regulation; NYU Langone Health must require the Investigator(s) involved to disclose the PHS Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.
- (iv) Public Access and Conflicts Reporting. The PHS Regulations impose public access and reporting requirements with respect to a PHS Conflict of Interest. Public access requirements include posting certain information about a PHS Conflict of Interest that NYU Langone Health's placement on a publicly accessible Web site or provision of a written response to any requestor within five (5) business days. Conflicts reporting includes reporting obligations related to a PHS Conflict of Interest prior to NYU Langone Health's expenditure of any funds for the project, reporting obligations related

to PHS Conflict of Interest subsequent to the initial reporting (including annual FCOI reports) or for PHS Conflict of Interest later disclosed or identified during a project, and reporting obligations related to a conflict mitigation plan or retrospective review. The CIMU, in collaboration with SPA and the principal investigator/project director of the applicable PHS Sponsored Project, is responsible for complying with any public access, reporting and/or other requirements required by the PHS Regulations arising from a finding of a PHS Conflict of Interest.

The procedures governing NYU Langone Health's review, evaluation, conflict management plans, retrospective reviews, mitigation reports, public access, and conflicts reporting for projects covered by the PHS Regulations are outlined in NYU Langone Health's *Procedures on Conflicts of Interest in Research and Sponsored Programs covered by the PHS Regulations*.

VIII. **Sub-recipients**

Investigators outside of the NYU Langone Community (e.g., sub-grantees, sub-contractors, collaborators or consultants) may also have Conflicts of Interest in a Sponsored Project. NYU Langone Health may subject any Investigators outside of the NYU Langone Community to the pertinent portions of this Policy and will subject such Investigator to this Policy when required by the Research Sponsor. In such cases, the outside Investigator's institution must represent in writing that it has a written conflicts policy in effect that applies to its investigators, that the policy complies with all applicable Research Sponsor requirements, and that it will report applicable conflicts of interest to NYU Langone Health in the time period and including the disclosure requirements required by the Research Sponsor. If the institution cannot make this representation, the outside Investigator must agree to comply with this Policy, in which case NYU Langone Health's Chief Scientific Officer shall have discretion to determine how this Policy should be implemented and/or adjusted for the specific Sponsored Project. Additional procedures governing NYU Langone Health's use of Investigators outside of the NYU Langone Community in projects covered by the PHS Regulations are outlined in NYU Langone Health's *Procedures on Conflicts of Interest in Research and Sponsored Programs covered by the PHS Regulations*.

IX. **Training**

Investigators involved in a Sponsored Project may be required by the CIMU and/or a Research Sponsor to periodically complete an appropriate conflict of interest training program prior to engaging in a Sponsored Project. For example, each Investigator participating in a PHS Sponsored Project must complete training regarding this Policy and the PHS Regulations prior to engaging in a PHS Sponsored Project, at least every four years thereafter, and as otherwise may be required by the CIMU.

X. **Definitions**

A. "**Compelling Circumstances**" means those facts that convince the Chief Scientific Officer and/or the CIMU that an Investigator may participate in a Sponsored Project despite the existence of a Significant Financial Interest. Factors that may be evaluated by the CIMU in determining whether Compelling Circumstances are present are listed in NYU Langone Health's *Procedures on Research Conflict of Interest and Sponsored Programs*.

B. A "**Conflict of Interest**" exists in a Sponsored Project when NYU Langone Health's designated officials reasonably determine that an Investigator's Financial Interest could affect or be affected, or appear to affect or be affected, by the design, conduct or reporting of the Sponsored Project.

C. A "**Financial Interest**" is held when an Investigator or a member of his or her Immediate Family has a personal financial interest that reasonably appears to be related to the Investigator's Institutional Responsibilities with NYU Langone Health and includes all personal financial interests 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 Management, Board, or Employment Position, Ownership Interests, Consulting Compensation, Paid/Reimbursed Travel, Royalty Income, and Intellectual Property Rights, where:

- (i) A “**Management, Board, or Employment Position**” means a position or appointment to serve, in either a personal or representative capacity, as a director, trustee, partner, executive, manager, officer, employee, or equivalent, 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 diversified investment vehicles, such as broad-based publicly-traded, diversified 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 a Management, Board, or Employment Position in the vehicle, are not Ownership Interests.)
- (iii) “**Consulting Compensation**” means salary, consulting fees, honoraria, paid authorship, 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 in connection with a Management, Board, or Employment Position or 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) “**Paid/Reimbursed Travel**” means the occurrence and value of any paid/sponsored (i.e., sponsored travel is 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), and/or reimbursed travel, whether in connection with a Management, Board, or Employment Position or 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 (i.e., no less than the past 12 months) or are expected to be received in the current or next calendar year.
- (v) “**Royalty Income**” means payments linked to product sales, or the written contractual right to receive future royalties, directly or indirectly, under an issued or pending patent, license or copyright, that has been received in the past calendar year or is expected to be received in the current or next calendar year. For the purpose of this Policy, Royalty Income includes all income received by an Investigator from NYU in accordance with the NYU’s intellectual property policies, including its [Statement of Policy on Intellectual Property](#).
- (vi) 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’s intellectual property policies, including its [Statement of Policy on Intellectual Property](#)).

The following are **not** Financial Interests under this Policy:

- (a) Salary from NYU Langone Health and cost-related payments for services or reimbursements from NYU Langone Health.

(b) Payments to NYU Langone Health, or via NYU Langone Health to the Investigator, which are directly related to the reasonable costs incurred in the conduct of a Sponsored Project or to the payment of indirect costs and are specified in a grant, agreement or contract between NYU Langone Health and the Research Sponsor.

(c) Income or Paid/Reimbursed Travel from seminars, lectures, or teaching engagements sponsored by, and income from service on advisory committees or review panels for, 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.

D. “**Financially-Interested Company**” means an outside entity which would reasonably appear to affect or be affected by the conduct or outcome of a Sponsored Project at NYU Langone Health. 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 research involving an Investigator’s intervention or interaction with a living human individual or with an individual’s identifiable information at or under the auspices of NYU Langone Health as defined by the IRB under its policies.

F. “**Immediate Family**” means the person’s spouse, domestic partner, person in a civil union or similar relationship, dependent children, or other family members residing in the person’s household.

G. “**Institutional Responsibilities**” means an Investigator’s professional responsibilities on behalf of NYU Langone Health, 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.

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

I. An “**Investigator**” is any person in the NYU Langone Community, regardless of title or position, who is any of the following in connection with a Sponsored Project at or under the auspices of NYU Langone Health:

1. Responsible for the designing, conducting or reporting of the Sponsored Project;
2. Proposing to be the principal investigator/program director, or key personnel in a grant application for the Sponsored Project submitted by NYU Langone Health;
3. Serving as the principal investigator/program director, co-investigator, sub-investigator, or key personnel on the Sponsored Project; or
4. Listed as an investigator or coordinator on an IRB application for the Sponsored Project.

Investigator also includes outside persons (e.g., sub-grantees, contractors, collaborators or consultants of NYU Langone Health) who are determined by NYU Langone Health, in consultation with the principal investigator/program director of the Sponsored Project, to be responsible for the design, conduct, or reporting of the Sponsored Project conducted at or under the auspices of NYU Langone Health. Section VIII of this Policy outlines the circumstances under which such outside Investigators will be required to comply with the

pertinent portions of this Policy.

J. **“Non-Human Subjects Research”** means any basic research, animal research, and other research conducted at or under the auspices of NYU Langone Health that is not Human Subjects Research, regardless of the source of funding.

K. **“NYU Langone Health”** includes NYU Langone Health System, NYU Langone Hospitals (including all inpatient and ambulatory facilities), NYU Grossman School of Medicine, NYU Long Island School of Medicine, and all entities that are controlled by any of them, except where specifically excluded. This Policy also has been adopted by the Family Health Centers at NYU Langone; therefore, for purposes of this Policy, “NYU Langone Health” also includes the Family Health Centers at NYU Langone.

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

M. **“Office of Science & Research”** means NYU Langone Health’s Office of Science & Research. The offices in the Office of Science & Research that may be responsible for the review and administration of a Sponsored Project proposal include the Office of Sponsored Programs Administration (SPA), the Clinical Research Support Unit (CRSU), the Office of Industrial Liaison (OIL), the Institutional Review Board (IRB), the Institutional Animal Care and Use Committee (IACUC), and the Institutional Biosafety Committee (IBC).

N. **“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). See Section VII.A for a list of other PHS agencies.

O. **“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 and Responsible Prospective Contractors,” (see: <http://grants.nih.gov/grants/policy/coi/>), as the same may be amended from time to time.

P. **“PHS Sponsored Projects”** means Sponsored Projects subject to the PHS Regulations.

Q. **“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.

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

S. **“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 Management, Board, or Employment Position (including as a director, trustee, partner, senior executive, officer or employee); (b) Ownership Interests (including stocks, options and warrants) of greater than \$10,000 in a publicly-held company; (c) Ownership Interests of any amount in a privately-held company; (d) Consulting Compensation (including salary, consulting income and honoraria), Paid/Reimbursed Travel for personal benefit as determined by the CIMU (e.g., a gift or a trip whose primary purpose is pleasure or celebration), and Royalty Income, when aggregated, of greater than \$25,000 in any relevant year; or (e) any Intellectual Property Right being tested,

developed, or validated in the Human Subjects Research.

- (ii) For a Pre-Clinical Research project, a Financial Interest is a “**Significant Financial Interest**” if it is (a) any Management, Board, or Employment; (b) Ownership Interests of greater than \$10,000 in a publicly-held company; (c) Ownership Interest of any amount in a privately-held company; or (d) Consulting Compensation, Paid/Reimbursed Travel for personal benefit as determined by the CIMU, and Royalty Income, when aggregated, of greater than \$25,000 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; (b) Ownership Interests of greater than \$25,000 in a publicly-held company; (c) Ownership Interests of any amount in a privately-held company, or (d) Consulting Compensation, Paid/Reimbursed Travel for personal benefit as determined by the CIMU, and Royalty Income, when aggregated, of greater than \$40,000 in any relevant year.

The PHS definition of significant financial interest is applicable for PHS Sponsored Projects and is outlined in NYU Langone Health’s *Procedures on Conflicts of Interest in Research and Sponsored Programs covered by the PHS Regulations*.

T. “**Sponsored Program**” means any activity conducted at or under the auspices of NYU Langone Health that receives funding from outside NYU Langone Health 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.)

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

XI. **Enforcement**

A. Violations of this Policy are subject to disciplinary action, up to and including termination of employment or association with NYU Langone Health, in accordance with NYU Langone Health 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 NYU Langone Health 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) completed and submitted an annual disclosure as provided in the *Policy on Conflicts of Interest in Business Affairs* within the previous twelve (12) months and (ii) completed and submitted an investigator financial interest disclosure 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 Chief Scientific Officer that the failure of an Investigator to comply with this Policy has biased the design, conduct, or reporting of a Sponsored Project, NYU Langone Health will promptly notify the Research 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 Sponsored Project.

D. In addition, in any case where the Sponsored Project’s purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment and the Sponsored Project has been designed, conducted or reported by an Investigator with a Conflict of Interest that was not managed or reported to NYU Langone Health as required, the CIMU will notify the Chief Scientific Officer. Additionally, the CIMU may require

the Investigator involved to disclose the Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

XII. Administration

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

B. Reporting. The CIMU must provide reports of its activities under this Policy to the Chief Scientific Officer and NYU Langone Health's Business Conflict of Interest Committee on an annual basis.

C. Records Retention. Records related to this Policy will be maintained in accordance with NYU Langone Health's Policy on Record Retention as in effect from time to time. In addition, the CIMU will maintain records of all disclosures it receives, all determinations made, all conflict 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. Additional procedures governing NYU Langone Health's records retention responsibilities for projects covered by the PHS Regulations are outlined in NYU Langone Health's *Procedures on Conflicts of Interest in Research and Sponsored Programs covered by the PHS Regulations*.

XIII. Relationship to Other Policies

A. This Policy replaces the *Policy on Conflicts of Interest in Research and Sponsored Programs* dated April 1, 2009, as previously updated August 24, 2012, August 1, 2014, November 1, 2016, December 1, 2017, and October 17, 2018.

A. This Policy is intended to supplement, but not replace, other policies and guidelines applicable to the Investigator, including NYU Langone Health's *Policies on Conflicts of Interest, Commitment and Consulting*.

B. This Policy is intended to implement for NYU Langone Health the applicable provisions of the NYU Policy on Academic Conflicts of Interest and Conflicts of Commitment dated August 24, 2012, as it may be updated from time to time. This Policy, together with NYU Langone Health's *Procedures on Conflicts of Interest in Research and Sponsored Programs covered by the PHS Regulations*, is also intended, without reference to other NYU and/or NYU Langone Health policies, to meet NYU Langone Health's obligations to maintain a policy on financial conflicts of interest in research funded by federal sponsoring agencies (including PHS and the National Science Foundation).