





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.

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.



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 will







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

(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.

(iv) “PHS Significant Financial Interest” means:

(a) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

(1) With regard to any publicly traded entity, a PHS Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(2) With regard to any non-publicly traded entity, a PHS Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(3) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or

(b) The occurrence in the twelve (12) months preceding the disclosure of 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 their Institutional Responsibilities; provided, however, that this does not apply to travel that is reimbursed or 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.

(v) The following are not PHS Significant Financial Interests under this Policy:

(a) salary, royalties, or other remuneration paid by New York University or NYU Langone Health to the Investigator if the Investigator is currently employed or otherwise appointed by New York University or NYU Langone Health, including intellectual property rights assigned to New York University or NYU Langone Health and agreements to share in royalties related

to such rights;

(b) income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;

(c)





## Procedures on Conflicts of Interest in Research and Sponsored Programs Covered by the PHS Regulations

*Issuing Department:*  
Conflict of Interest Management Unit

*Effective Date:* December 5, 2014  
*Last Update:* August 24, 2018

### I. Summary

NYU Langone Health's *Policy on Conflicts of Interest in Research and Sponsored Programs* (the Policy) sets forth NYU Langone Health's policies on the disclosure, review, evaluation and determinations related to potential conflicts of interests arising out of NYU Langone Health's research and other sponsored programs. Under Section VI.A of the Policy, it is the policy of NYU Langone Health to comply with all rules about conflicts of interest imposed by Research Sponsors as a condition of providing funding to NYU Langone Health. These Procedures are intended to ensure compliance with the regulations adopted by the Public Health Service of the U.S. Department of Health and Human Services (the PHS Regulations). These Procedures supplement the Policy and apply to all Sponsored Projects subject to the PHS Regulations.

### II. Definitions

Capitalized terms not defined in these Procedures are defined in NYU Langone Health's *Policy on Conflicts of Interest in Research and Sponsored Programs*.

A. As provided in Section IX.M of the Policy, "**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.

The following offices/agencies are part of PHS:

- Administration for Children and Families (ACF)
- Administration for Community Living (ACL)
- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indidmt SsiSA)
-



- (c) 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; and
- (d) 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.

E. “**PHS Sponsored Project**” means any Sponsored Project subject to the PHS Regulations, including any Sponsored Project funded by PHS (e.g., the NIH) that is covered by the requirements of the PHS regulations, and any Sponsored Project funded by a non-PHS Research Sponsor that has incorporated the requirements of the PHS Regulations.

### III. **Disclosure**

Section IV of the Policy outlines the disclosure requirements for Investigators participating in Sponsored Projects conducted at or under the auspices of NYU Langone Health. These disclosure requirements apply to Investigators participating in PHS Sponsored Projects.

In addition to the requirements in Section IV of the Policy, for disclosures of Financial Interests in the form of Paid/Reimbursed Travel by Investigator in PHS Sponsored Projects, such disclosures must specify 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.

### IV. **Review and Evaluation of Disclosures**

Section V of the Policy outlines the procedures under which NYU Langone Health reviews and evaluates each disclosure made by an Investigator participating in a Sponsored Project to determine if a disclosed Financial Interest could give rise to a Conflict of Interest in the Sponsored Project and to review and evaluate the Travel by I p-2.6 ( b)2 (y)12.0.017 Te6 (er)-1. (t)-2.(ed)2 2 (b)2 (7 (n)2 (an)2 e.6 (n)2 (( I)19..0.01-6 (9







D. Research Conflict of Interest Committee. Any matter under this Procedure may be presented by CIMU, in its discretion, for an advisory review and evaluation by NYU Langone Health's Research Conflict of Interest Committee (RCOIC).

E. Appeals to the Senior Vice President and Vice Dean for Science. In accordance with Section V.D. of the Policy, determinations by the CIMU related to a finding of PHS Conflict of Interest may be appealed to NYU Langone Health's Senior Vice President and Vice Dean for Science. Appeals must be in accordance with the requirements of Section V.D. of the Policy. Decisions of the Senior Vice President and Vice Dean for Science are final.

F. Timing. The disclosure, review and evaluation of an Investigator's disclosure of a Financial Interest related to a PHS Sponsored Project and the issuance and implementation of any conflict



policy of the subrecipient will apply to the subrecipient, contractor or collaborator's Investigator(s). If the subrecipient, contractor or collaborator relies on its conflicts of interest policy, the subrecipient, contractor or collaborator will certify as part of the subrecipient agreement, that its policy complies with 42 CFR Part 50 and 45 CFR Part 94, as appropriate. In either case, the subaward will include time periods



X. **Questions**

Any questions relating to this Policy should be directed to the Office of Research Integrity at 2025 L Street, NW, Washington, DC 20541, or by email at [ORI@hhs.gov](mailto:ORI@hhs.gov).