

NYU LANGONE MEDICAL CENTER

PROCEDURES ON CONFLICTS OF INTEREST IN RESEARCH AND SPONSORED PROGRAMS COVERED BY THE PHS REGULATIONS

Issue Date: December 5, 2014

I. Summary

The Medical Center's *Policy on Conflicts of Interest in Research and Sponsored Programs* (the Policy) sets forth the Medical Center's policies on the disclosure, review, evaluation and determinations related to potential conflicts of interests arising out of the Medical Center's research and other sponsored programs. Under Section VI.A of the Policy, it is the policy of the Medical Center to comply with all rules about conflicts of interest imposed by Research Sponsors as a condition of providing funding to the Medical Center. 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 the Medical Center'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:

- 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)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- Office of the Assistant Secretary for Health (ASH)
- Office of the Assistant Secretary for Preparedness and Response (ASPR)
- Office of Global Affairs (OGA)

B. As provided in Sections VI.B(i) and IX.N of the Policy, a "**PHS Conflict of Interest**" exists when the Medical Center's designated official(s) reasonably determines that a Financial Interest that rises to a PHS Significant Financial Interest could *directly and significantly* affect the design, conduct, or reporting of a Sponsored Project subject to the PHS Regulations.

C. As provided in Section IX.O of the Policy, "**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.

D. “**PHS Significant Financial Interest**” means:

- (i) 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:
 - (a) 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;
 - (b) 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
 - (c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or
- (ii) 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.

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

- (a) salary, royalties, or other remuneration paid by the Medical Center to the Investigator if the Investigator is currently employed or otherwise appointed by the Medical Center, including intellectual property rights assigned to the Medical Center 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) 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 the Medical Center. 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 the Medical Center 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 disclosure to determine if the Investigator may participate in the Sponsored Project and, if participation is permitted, to implement a conflict management plan. These review and evaluation requirements apply to disclosures by Investigators participating in PHS Sponsored Projects.

In addition to the requirements outlined in Section V of the Policy, the following additional procedures apply for disclosures by Investigators participating in PHS Sponsored Projects:

A. **CIMU’s Initial Review.** Pursuant to Sections V.A of the Policy, the Conflict of Interest Management Unit (CIMU) has responsibility for the review and evaluation of each disclosure of Financial Interest to determine if a potential Conflict of Interest exists. In addition to the requirements outlined in Section V.A of the Policy, the CIMU is responsible for Investigators in PHS Sponsored Projects for determining (i) whether any disclosed Financial Interest is a PHS Significant Financial Interest, and (ii) whether any PHS Significant Financial Interest is “related” to a PHS Sponsored Project and could give rise to a PHS Conflict of Interest in a PHS Sponsored Project.

- (i) **No PHS Significant Financial Interest.** When CIMU determines that all disclosures of Financial Interests for a Sponsored Project are not PHS Significant Financial Interests, the CIMU will advise the Office of Sponsored Programs Administration that there is no PHS Conflict of Interest present.

(ii) **“Relatedness” and PHS Conflict of Interest.**

- a. When CIMU determines that certain disclosures are PHS Significant Financial Interests, the CIMU will determine if the Investigator’s PHS Significant Financial Interests are “related” to the PHS Sponsored Project.
- b. An Investigator’s PHS Significant Financial Interest is “related” to PHS Sponsored Project when the CIMU reasonably determines that the PHS Significant Financial Interest could affect or be affected, or appear to affect or be affected, by the PHS Sponsored Project or is in an entity whose financial interest could affect or be affected, or appear to affect or be affected, by the research.
- c. For disclosures of PHS Significant Financial Interest that the CIMU determines are “related” to a specific PHS Sponsored Project, the CIMU will review and evaluate the matter as a potential PHS Conflict of Interest under Section IV.B. below.
- d. For disclosures of PHS Significant Financial Interest that the CIMU determines are not “related” to the PHS Sponsored Project, the CIMU will advise the Office of Sponsored Programs Administration and the Investigator, as appropriate, that there is no “related” PHS Significant Financial Interest present and no PHS Conflict of Interest.

The CIMU may involve the Investigator, the Investigator’s department, the Research Conflict of Interest Committee, the Office of Science & Research and/or the Office of Legal Counsel in its evaluations under this Section IV.A.

B. CIMU’s PHS Conflict of Interest Findings. For disclosures of PHS Significant Financial Interest that the CIMU determines are “related” to a specific PHS Sponsored Project in Section IV.A. above, the CIMU must determine if the disclosure could give rise to a PHS Conflict of Interest in the PHS Sponsored Project. A PHS Conflict of Interest exists when the CIMU reasonably determines that the PHS Significant Financial Interest could *directly and significantly* affect the design, conduct, or reporting of the PHS Sponsored Project.

In determining whether an Investigator’s PHS Significant Financial Interest could create a PHS Conflict of Interest, the CIMU will consider the role of the Investigator and the opportunity (if any) to bias the results, the nature of the research being proposed, and the value of the PHS Significant Financial Interest in relation to the size and value of the entity. In addition, the CIMU may also consider the following factors:

1. The magnitude of the PHS Significant Financial Interests (e.g., the amount of consulting, or the percentage or value of equity); or
2. The number and nature of relationships an Investigator has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts; or
3. Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or
4. Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the PHS Significant Financial Interest; or

5. Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or
6. Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has a PHS Significant Financial Interest; or
7. Where the PHS Significant Financial Interest is in the sponsor of the research, and the sponsor is a licensee of the Investigator's technology, the amount of commercialization payments received by the faculty member from that technology, both currently or in the future; or
8. Whether the goal of the research is to evaluate an invention linked to the PHS Significant Financial Interest (such as where the PHS Significant Financial Interest is a patent, or an interest in a company that has licensed the invention); or
9. Whether the research involves human subjects; or
10. Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board; or
11. Where the PHS Significant Financial Interest is in a privately held company, whether the research could have a significant impact on the company's business or financial outlook or whether the Investigator's PHS Significant Financial Interest could result in the Investigator having influence over company decisions; or
12. Whether other scientific groups are independently pursuing similar questions; or
13. Whether sufficient external review of the research conducted and the reporting of research results exist to mitigate undue bias; or
14. Whether the project involves a subaward to an entity in which the Investigator has a PHS Significant Financial Interest.

For all reviews of potential PHS Conflict of Interest, the CIMU's finding will be documented and will be included in any conflict management plan approved by the CIMU under Section IV.C. below.

The CIMU may involve the Investigator, the Investigator's department, the Research Conflict of Interest Committee, the Office of Science & Research and/or the Office of Legal Counsel in its evaluations under this Section IV.B.

C. PHS Conflict Management Plan. Section V.B. of the Policy outlines the procedures related to conflict management plans issued by the CIMU in the event an Investigator's participation in a PHS Sponsored Project is permitted notwithstanding a PHS Conflict of Interest. There are no additional requirements for PHS Sponsored Projects other than that the CIMU's finding of a PHS Conflict of Interest will be included in the conflict management plan approved by the CIMU. The CIMU is responsible for monitoring the compliance with all PHS conflict management plan on an ongoing basis until the completion of the PHS Sponsored Project.

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 the Medical Center'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 the Medical Center'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 management plan as outlined above must be completed prior to any expenditure on the PHS Sponsored Project or the commencement of the Investigator's involvement in the PHS Sponsored Project. For disclosures prior to the commencement of the PHS Sponsored Project, no expenditures on PHS Sponsored Project will be permitted until the Investigator has complied with the disclosure requirements of the Policy and has agreed, in writing, to comply with any plans determined by the CIMU necessary to manage the PHS Conflict of Interest.

G. Reporting. The CIMU will communicate with the PHS Awarding Component to notify it of the existence and the nature of a PHS Conflict of Interest and whether the PHS Conflict of Interest has been managed, reduced, or eliminated. See Section VI below.

H. Record-Keeping. The CIMU will keep a record of Investigator disclosures of financial interests and any review of, and response to, such disclosure and all actions under this Procedure. Such records will be maintained and kept for three years from the date the final expenditures report is submitted for grants, for three years from the date of final payment for contracts, or, where applicable, for time periods as otherwise specified in relevant PHS Regulations.

V. **Public Accessibility to Information Related to PHS Conflicts of Interest**

Prior to the expenditure of any funds under a PHS-funded research project, the CIMU, on behalf of the Medical Center, will ensure public accessibility, by written response to any requestor within five (5) business days of a request, of information concerning any PHS Significant Financial Interest disclosed that meets the following three criteria:

- (i) The PHS Significant Financial Interest was disclosed and is still held by the senior/key personnel. Senior/key personnel are the PD/PI and any other person identified as senior key personnel by the Medical Center in the grant application, progress report or any other report submitted to the PHS by the Medical Center;
- (ii) The CIMU has determined that the PHS Significant Financial Interest is "related" to the PHS Sponsored Project (see Section IV.A(ii) above); and
- (iii) The CIMU has determined that the PHS Significant Financial Interest is a PHS Conflict of Interest.

The information that the CIMU, on behalf of the Medical Center, will make available in a written response to any requestor within five (5) business days of request will include, at a minimum, the following:

- (i) The Investigator's name;
- (ii) The Investigator's title and role with respect to the research project;
- (iii) The name of the entity in which the PHS Significant Financial Interest is held;

- (iv) The nature of the PHS Significant Financial Interest;
- (v) The approximate dollar value of the PHS Significant Financial Interest in the following ranges: \$0-\$4,999; \$5,000-9,999; \$10,000 - \$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value; and
- (vi) A description of how the financial interest relates to NIH-funded research and the basis for the Medical Center's determination that the PHS Significant Financial Interest conflicts with such research.

When the Medical Center responds to written requests for the purposes of public accessibility, it will ascertain from the Investigator that the information provided is current as of the date of the correspondence, and will note in its written response that the information is subject to updates, on at least an annual basis and within sixty (60) days of the Medical Center's identification of a new PHS Conflict of Interest, which should be requested subsequently by the requestor.

Information concerning a PHS Conflict of Interest will remain available, for responses to written requests for at least three (3) years from the date that the information was most recently updated.

VI. Reporting of PHS Conflicts of Interest

Prior to the expenditure of any funds under a PHS Sponsored Project, the CIMU, in collaboration with the Office of Sponsored Programs Administration, will provide to the PHS Awarding Component a PHS Conflict of Interest report (i.e., a new FCOI report) compliant with PHS Regulations regarding any Investigator's PHS Significant Financial Interest found to give rise to a PHS Conflict of Interest and will ensure that the Investigator has agreed to and implemented the corresponding management plan. While the award is ongoing (including any extensions with or without funds), the CIMU, in collaboration with the Office of Sponsored Programs Administration, will provide to the PHS Awarding Component an annual PHS Conflict of Interest report that addresses the status of the PHS Conflict of Interest (i.e., whether conflict is still being managed or why it no longer exists) and any changes in the management plan.

For any PHS Significant Financial Interest that is identified as conflicting subsequent to an initial PHS Conflict of Interest report during an ongoing PHS Sponsored Project (e.g., upon the participation of an Investigator who is new to the research project or a new PHS Significant Financial Interest), the Medical Center will provide to the PHS Awarding Component, within sixty days, a new PHS Conflict of Interest report regarding the PHS Conflict of Interest and ensure that the Medical Center has implemented a management plan and the Investigator has agreed to the relevant management plan.

VII. Subrecipient Requirements

The Medical Center will, as part of a written subaward with a subrecipient, contractor or collaborator under a PHS prime award, establish whether the Policy applies or whether the financial conflict of interest 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 to meet the disclosure and/or financial conflict of interest reporting requirements of the Medical Center under the PHS Regulations. The subrecipient, contractor or collaborator's institution shall be responsible for having its relevant Investigators provide to the Medical Center the appropriate disclosures at the time of application or as required.

Pursuant to Section VII of the Policy, if the subrecipient cannot make this representation, the outside Investigator must agree to comply with this Policy, in which case the Medical Center's Senior Vice President and Vice Dean for Science will have discretion to determine how this Policy should be implemented and/or adjusted for the specific PHS Sponsored Project.

Consistent with the PHS Regulations, the Medical Center will make publicly accessible any PHS Conflicts of Interest involving a subrecipient, contractor or collaborator investigator as outlined in Section V above and will report each PHS Conflict of Interest involving subrecipient, contractor or collaborator investigator as outlined in Section VI above.

VIII. Training Requirements

Each Investigator must complete training on the Medical Center's *Policy on Conflict of Interest in Research and Sponsored Programs* prior to engaging in a PHS Sponsored Project and when any of the following circumstances apply:

- 1) The Medical Center revises the Policy or these Procedures in any manner that affects the requirements of Investigators (training will be completed in the manner and within the time frame specified in communications by CIMU announcing such changes);
- 2) An Investigator is new to the Medical Center (training must be completed within 30 days of joining the Medical Center); or
- 3) The Medical Center finds that an Investigator is not in compliance with this Procedure to the Medical Center's Conflict of Interest Policy or a management plan issued under this Procedure (training must be completed within 30 days in the manner specified by the CIMU).

In addition, each Investigator must complete the training at least every four years and as otherwise may be required by the CIMU.

IX. Failure to Comply

Section VI(B)(iv) of the Policy outline the consequences for failures to timely disclose or review a PHS Conflict of Interest. In addition to such requirements, the following procedures apply for failures to timely disclose or review a PHS Conflict of Interest in PHS Sponsored Projects:

A. Late Disclosures. Whenever, in the course of an ongoing PHS Sponsored Project, an Investigator who is new to participating in the project discloses a PHS Significant Financial Interest or an existing Investigator discloses a new PHS Significant Financial Interest to the Medical Center, the CIMU will, within sixty (60) days: review the disclosure of the PHS Significant Financial Interest; determine whether it is "related" to PHS Sponsored Project; determine whether a PHS Conflict of Interest exists; and, if so, implement, on at least an interim basis, a conflict management plan that will specify the actions that have been, and will be, taken to manage such PHS Conflict of Interest. Depending on the nature of the PHS Significant Financial Interest, the CIMU may determine that additional interim measures are necessary with regard to the Medical Center's participation in the PHS Sponsored Project between the date of disclosure and the completion of the Medical Center's review. For PHS Sponsored Projects requiring IRB review, these conflict management plans are to be considered as part of the IRB's review.

B. Review and Mitigation. Whenever the Medical Center identifies a PHS Significant Financial Interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously

reviewed by the Medical Center during an ongoing PHS Sponsored Project (e.g., was not timely reviewed or reported by a subrecipient), CIMU will, within sixty (60) days: review the significant financial interest; determine whether it is related to PHS Sponsored Project; and determine whether a PHS Conflict of Interest exists. If so, CIMU will implement, on at least an interim basis, a conflict mitigation plan that will specify the actions that have been, and will be, taken to manage such PHS Conflict of Interest going forward. For PHS Sponsored Projects requiring IRB review, these conflict mitigation plans are to be considered as part of the IRB's review. The CIMU is responsible for monitoring the compliance with the conflict mitigation plan on an ongoing basis until the completion of the PHS Sponsored Project.

C. Retrospective Review. In addition, whenever a PHS Conflict of Interest is not identified or managed in a timely manner including failure by the Investigator to disclose a PHS Significant Financial Interest that is determined by the Medical Center to constitute a PHS Conflict of Interest; failure by the Medical Center to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the CIMU will, within 120 days of the Medical Center's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS Sponsored Project(s) to determine whether any PHS Sponsored Project, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

The CIMU must document the retrospective review. Such documentation will include, but not necessarily be limited to, all of the following key elements: (1) Project number; (2) Project title; (3) PD/PI or contact PD/PI if a multiple PD/PI model is used; (4) Name of the Investigator with the PHS Conflict of Interest; (5) Name of the entity with which the Investigator has a financial conflict of interest; (6) Reason(s) for the retrospective review; (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed); (8) Findings of the review; and (9) Conclusions of the review.

Based on the results of the retrospective review, if appropriate, the CIMU will update the previously submitted PHS Conflict of Interest report, specifying the actions that will be taken to manage the PHS Conflict of Interest going forward. If bias is found, the CIMU will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the Sponsored Project and the Medical Center's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; and/or analysis of whether the research project is salvageable). Thereafter, the CIMU will submit PHS Conflict of Interest reports annually, as specified elsewhere in this Procedure.

Depending on the nature of the PHS Conflict of Interest, the CIMU may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS Sponsored Project between the date that the PHS Conflict of Interest or the Investigator's noncompliance is determined and the completion of the retrospective review.