

NYU LANGONE

POLICY ON INSTITUTIONAL CONFLICTS OF INTEREST IN HUMAN SUBJECTS RESEARCH

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I. Summary

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

NYU Langone'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 the NYU Langone and members of the NYU Langone Community, as well as the conduct of NYU Langone's business. This Policy is a part of the *Policies* and sets forth NYU Langone's policies governing when it will participate in a human subjects research project despite the existence of a financial interest held by New York University (NYU) or NYU Langone in the product being tested in the project or in the for-profit research sponsor of the project.

Under this Policy, NYU Langone must identify when an Institutional Financial Interest (as defined below) may affect or appear to affect the design, conduct, reporting, review, or oversight of a human subjects research project. NYU Langone, through its Conflict of Interest Management Unit (CIMU), will then review and evaluate such interests, determine if an institutional conflict of interest exists, and determine whether such institutional conflict can be managed or eliminated in order to permit NYU Langone to engage in the project.

II. Applicability

This Policy applies to all Investigators participating in human subjects research conducted at or under the auspices of NYU Langone. All capitalized terms shall have the meaning set forth in Section VI below.

III. General Policy

A. An “**Institutional Conflict of Interest**” arises in human subjects research when a financial interest of NYU or NYU Langone may affect or appear to affect the design, conduct, reporting, review, or oversight of the human subjects research. Institutional Conflicts of Interest are of significant concern when an Institutional Financial Interest (as defined below) creates the potential for inappropriate influence over a human subjects research project, particularly to the integrity of the research and the safety and care of patients enrolled in the research.

B. An “**Institutional Financial Interest**” is held when either (i) NYU or NYU Langone receives or might reasonably be expected to receive royalty income from the sale of a product covered by any patent (whether issued or pending), copyright, license or other intellectual property right, held by NYU or NYU Langone and proposed to be used in the human subjects research project; and/or (ii) NYU or NYU Langone holds or proposes to hold, directly or indirectly, equity interests of any amount (or entitlement to the same), in the research sponsor for the human subjects research project, whether such research sponsor is public or non-public, through NYU’s or NYU Langone’s technology licensing activities or investments related to such activities.

C. All potential Institutional Conflict of Interests require disclosure, evaluation and either management or elimination under this Policy.

D. Certain Institutional Conflicts of Interest are too significant to manage and must be eliminated. As a matter of policy, NYU Langone will not participate in a human subjects research project that involves a significant Institutional Conflict of Interest, such as (i) a clinical trial, or other human subjects research project of greater than minimal risk, testing, validating or developing a product covered by an NYU or NYU Langone intellectual property right or (ii) a clinical trial sponsored by a for-profit company in which NYU or NYU Langone holds or proposes to hold any equity interests. An exception to this policy may be made only when diligent efforts to eliminate the conflict do not succeed, or when NYU Langone’s Business Conflict of Interest Committee, Senior Vice President and Vice Dean for Science and/or CIMU determines that facts and 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. Reporting

A. The Office of Industrial Liaison (OIL) will periodically develop a list of Institutional Financial Interests, including (i) all drugs, devices and other possible investigational products covered by any patent (whether issued or pending), copyright, license or other intellectual property right held by NYU or NYU Langone which may be the subject of human subjects research at NYU Langone, and the entities that have licensed the intellectual property rights covering such drugs, devices and other investigational products, and (ii) the entities in which NYU or NYU Langone has acquired any equity interests (or entitlements to the same) of any amount through NYU’s or NYU Langone’s technology licensing activities.

B. The Office of Industrial Liaison will periodically provide such lists to the CIMU, the Clinical Research Support Unit (CRSU), the Office of Sponsored Programs Administration (SPA), and NYU Langone’s Institutional Review Board (IRB).

C. OIL, the CRSU, SPA, and NYU Langone’s IRB will review all proposed human subjects research projects against such lists to identify potential Institutional Conflicts of Interest and report identified matters to the CIMU.

V. Review and Evaluation

A. Conflict of Interest Management Unit (CIMU) Review. The CIMU is responsible for reviewing each disclosure of an Institutional Financial Interest in a human subjects research project and for determining whether an Institutional Conflict of Interest exists under the circumstances. In cases where the CIMU determines that a significant Institutional Conflict of Interest may exist, the CIMU, in consultation with the Office of Legal Counsel and the Vice Dean for Science, will make a determination on whether Compelling Circumstances exist to justify NYU Langone's participation in the project and on whether diligent efforts to eliminate the conflict have not succeeded. In other cases where CIMU determines that an Institutional Conflict of Interest may exist but is not of significant concern, the CIMU will normally determine that NYU Langone may participate in the project and issue a management plan as provided in Section V.B below.

B. Conflict Management Plan. If NYU Langone's participation in a project is permitted notwithstanding the Institutional Financial Interest, NYU Langone's participation is subject to a conflict management plan which maintains research integrity and serves the best interests of subjects enrolled in the research. Management strategies to be considered are listed in NYU Langone's *Procedures on Research Conflict of Interest and Sponsored Programs*. The conflict management plan must be agreed to by the principal investigator. Conflict management plans are to be considered as part of the IRB's review. The human subjects research cannot commence until IRB approval is released following receipt of the conflict management plan. The principal investigator on the human subjects research project must comply with all terms in the conflict management plan of the duration of the research. The CIMU is responsible for monitoring the compliance with the conflict management plan on an ongoing basis until the completion of the project.

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

D. Appeals to the Senior Vice President and Vice Dean for Science. Determinations of the CIMU may be appealed to NYU Langone's Vice Dean for Science. Appeals must be in writing and submitted to the CIMU. The CIMU will provide copies of the appeal to the Vice Dean for Science. Decisions of the Vice Dean for Science are final.

E. Timing. The review and evaluation of an Institutional Financial Interest as contemplated by this Policy shall be completed prior to the expenditure of any awarded funds for the human subjects research project or any commencement of the project (including enrollment of any research subjects).

VI. Definitions

A. "**Compelling Circumstances**" means those facts that convince the Vice Dean for Science and/or the CIMU that NYU Langone may participate in a human subjects research project despite the existence of an Institutional Financial Interest. Factors that may be evaluated by the CIMU in determining whether Compelling Circumstances are present are listed in NYU Langone's *Procedures on Research Conflict of Interest and Sponsored Programs*.

B. "**Institutional Conflict of Interest**" has the meaning set forth in Section III.A. above.

C. “**Institutional Financial Interest**” has the meaning set forth in Section III.B. above.

D. “**NYU Langone**” refers to NYU Langone Health System (the “System”), its subsidiary, NYU Hospitals Center (“NYUHC”), Affiliates of the System, and New York University School of Medicine (“NYUSOM”), an administrative division of New York University, and NYUSOM Affiliates. For purposes of this Policy, “Affiliate” means an entity under the direct or indirect control of the System or NYUSOM, whether now existing or hereafter created.

VII. **Enforcement**

Violations of this Policy are subject to disciplinary action, up to and including termination of employment or association with NYU Langone, in accordance with NYU Langone’s applicable disciplinary policies and procedures.

VII. **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 shall provide reports of its activities under this Policy to NYU Langone’s Business Conflict of Interest Committee and the Vice Dean for Science on an annual basis.

VIII. **Relationship to Other Policies**

A. This Policy replaces the *Policy on Institutional Conflicts of Interest in Human Subjects Research* dated April 1, 2009, as previously updated August 1, 2014.

B. This Policy is intended to supplement, but not replace, other policies and guidelines applicable to conflicts, including NYU Langone’s *Policies on Conflicts of Interest, Commitment and Consulting*.