

NYU LANGONE MEDICAL CENTER

POLICY ON INSTITUTIONAL CONFLICTS OF INTEREST IN HUMAN SUBJECTS RESEARCH

Issue Date: April 1, 2009

Contents:

- I. Purpose, Scope and Policy
 - II. Reporting
 - III. Review and Evaluation
 - IV. Examples of Institutional Conflicts of Interest
 - V. Enforcement
 - VI. Administration
-

I. Purpose, Scope and Policy

A. An “**Institutional Conflict of Interest**” arises in human subjects’ research when a financial interest of New York University (NYU) or the Medical Center 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. All potential Institutional Conflicts of Interest in human subjects’ research require disclosure, evaluation and either management or elimination under this Policy.

B. An “**Institutional Financial Interest**” is held when either (i) NYU or the Medical Center receives or might reasonably be expected to receive royalty income from the sale of a product covered by any patent, license or copyright, whether issued or pending, held by NYU or the Medical Center and proposed to be used in the human subjects’ research project; and/or (ii) NYU or the Medical Center holds or proposes to hold, directly or indirectly, any 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 the Medical Center’s technology licensing activities or investments related to such activities.

C. Certain Institutional Conflicts of Interest are too significant to manage and must be eliminated. As a matter of policy, the Medical Center will not participate in a human subjects’ research project when it has an Institutional Financial Interest. An exception to this policy may be made only when the Senior Vice President and Vice Dean for Science of the Medical Center or the Research Conflict of Interest Committee (RCOIC) determines that Compelling Circumstances (as defined below) 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.

D. Under this Policy, “**Compelling Circumstances**” means those facts that convince the Vice Dean for Science and the RCOIC that the Medical Center may participate in a human subjects’ research project despite the existence of an Institutional Financial Interest. Factors that may be evaluated by the RCOIC in determining whether Compelling Circumstances are present are listed in the *Research Conflict of*

Interest Committee - Operating Guidelines (Appendix B to the Medical Center's *Policies on Conflicts of Interest, Commitment and Consulting*).

II. **Reporting**

A. The Office of Industrial Liaison (OIL) shall periodically develop a list of Institutional Financial Interests, including (i) all drugs, devices and other possible investigational products covered by issued or pending patents, licenses or copyrights held by NYU or the Medical Center which may be the subject of human subjects' research at the Medical Center, and the entities that have licensed such drugs, devices and other investigational products, and (ii) the entities in which NYU or the Medical Center has acquired any equity interests (or entitlements to the same) of any amount through NYU's or the Medical Center's technology licensing activities.

B. The Office of Industrial Liaison shall periodically provide such lists to the Office of Clinical Trials (OCT), the Office of Sponsored Programs Administration (SPA), the School of Medicine's Institutional Review Board, and the Office of Compliance.

C. OIL, the OCT, SPA, and the Medical Center's IRB shall review all proposed human subjects' research projects against such lists to identify potential Institutional Conflicts of Interest and report identified matters to the Office of Compliance.

III. **Review and Evaluation**

A. Office of Compliance Review. The Office of Compliance 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 Office of Compliance determines that an Institutional Conflict of Interest may exist, the Office of Compliance will submit the matter to the RCOIC.

B. RCOIC Review. The RCOIC is responsible for reviewing and evaluating each potential Institutional Conflict of Interest matter submitted to it by the Office of Compliance. The RCOIC shall make a determination on whether Compelling Circumstances exist to justify the Medical Center's participation in the project.

C. Conflict Management Plan. If the Medical Center's participation in a project is permitted notwithstanding the Institutional Financial Interest, the Medical Center'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 the *Research Conflict of Interest Committee – Operating Guidelines* (Appendix B to the Medical Center's *Policies on Conflicts of Interest, Commitment and Consulting*). The conflict management plan shall be adopted by the RCOIC and agreed to by the principal investigator, and ratified by the IRB.

D. Appeals to the Senior Vice President and Vice Dean for Science. Appeals shall be in writing and submitted to the Office of Compliance. Appeals may be made by the Office of Compliance, the RCOIC, the Dean/CEO of the Medical Center, the Senior Vice President and Vice Dean for Science, or any Investigator on the project. The Office of Compliance will provide copies of the appeal to the Senior Vice President and Vice Dean for Science and the RCOIC Chair. Decisions of the Senior Vice President and Vice Dean for Science are final.

E. Timing. The review and evaluation of an 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)

IV. **Examples of Institutional Conflicts of Interest**

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

V. **Enforcement**

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

VI. **Administration**

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

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