

North Shore – LIJ Health System, Inc.

POLICY TITLE: Review and Management of Institutional Financial Conflict of Interest in Research	ADMINISTRATIVE POLICY AND PROCEDURE MANUAL
POLICY #: GR082	CATEGORY: Research
System Approval Date: 9/17/15	Effective Date: 9/19/13
Site Implementation Date:	Last Revised:
Prepared by: Office of Research Compliance, Legal Affairs, Research Administration	Superseded Policy(s)/#: N/A

GENERAL STATEMENT of PURPOSE

The purpose of this policy is to promote the identification, disclosure and, if required, resolution or management of potential *Institutional Conflicts* at the health system in the context of research. It is the desire of The Feinstein Institute for Medical Research (“the Feinstein”) and the North Shore-Long Island Jewish Health System, Inc. (“Health System”) to eliminate, reduce or mitigate any external interest that may create the potential for undue influence on decision making in the conduct of business or compromise the objectivity of research.

The process for evaluation of *individual* conflicts of interest is currently addressed by the Health System through NSLIJHS Policies #800.03 Conflict of Interest and Recusal and #GR065 Review and Management of Conflict of Interest in Research (Individual).

POLICY

It is the policy of the Health System that reasonable efforts are taken to avoid institutional conflicts of interest and comply with requirements of federal and state laws and/or regulations governing potential conflicts.

A potential institutional conflict of interest exists whenever the Feinstein, Health System or a Health System owned or controlled entity is engaged in the conduct of research activities with an external entity in which it also has a significant financial interest; or a key employee/institutional official, authorized to take actions on behalf of the institution, is engaged in the conduct of business or research activities with an external entity in which the institution has a significant financial interest. These potential conflicts may unduly influence or appear to influence decision making regarding institutional research activities.

Voluntary and timely disclosures of potential conflicts of interest must be made in order to allow the Feinstein or Health System to take steps to avoid the substance or appearance of an

institutional conflict of interest. Whenever a question as to the existence of an institutional conflict of interest arises, it is important that individuals or entities consult with the Office of Research Compliance.

SCOPE

This policy applies to faculty and students of the Hofstra North Shore-LIJ School of Medicine (“School of Medicine”) conducting work or research on behalf of the School of Medicine or at any North Shore-LIJ Health System facility; and all members of the North Shore – LIJ Health System workforce including, but not limited to, employees, medical staff, volunteers, students, physician office staff, and other persons performing work for or conducting research at or on behalf of the North Shore – LIJ Health System.

DEFINITIONS

Institutional Conflicts of Interest: A situation in which the financial interests of an institution or an key employee/institutional official, with authority to act on behalf of the institution, may affect or reasonably appear to affect research, education, clinical care, business transactions or other activities of the institution.

Disclosure: The provision of information about significant financial interests or external activities in connection with research activities occurring at North Shore-LIJ Health System facilities.

Health System Owned or Controlled entity: Any hospital or entity within the Health System that has the Health System, or an entity owned or controlled by the Health System as its sole corporate parent, and shares a common board of directors and management with the Health System, or is otherwise controlled by the Health System or an entity owned or controlled by the Health System.

Research Activity: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. This includes, but is not limited to, designing research, directing research, performing experiments, enrolling research subjects, making decisions regarding eligibility to participate in research, participating in observational registry programs, analyzing or reporting research data, or submitting manuscripts concerning research for publication. Activities which meet this definition constitute research for purposes of this Institutional Conflicts Policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include Research Activities.

PROCEDURE/GUIDELINES

Identification of Potential Institutional Conflicts of Interest (COI)

The following includes significant financial and fiduciary interests that warrant disclosure and may require formal review of potential institutional COI, as provided in this policy. Other interests involving material amounts or significant fiduciary interests may also warrant disclosure.

- A. Royalties that may result from licensing, technology transfer, or patents: institutional COI may be present when the institution has the potential to receive significant milestone payments and/or royalties from the sales of a product, i.e. payments/royalties in excess of \$100,000 per year.
- B. Non-publicly traded equity: When, through its technology licensing activities or investments related to such activities, the institution has obtained an equity interest or an entitlement to equity of any value (including options or warrants or as a result of startup ventures) in a *non-publicly traded* company that is i) the sponsor of research at the Feinstein, Health System or a Health System owned or controlled entity, or ii) the manufacturer of a product to be studied or tested in research at or under the auspices of the Feinstein, Health System or a Health System owned or controlled entity.
- C. Publicly traded equity: When, through technology licensing activities or investments related to such activities, the institution has obtained an ownership interest or an entitlement to equity (including options or warrants) exceeding \$100,000 in value (when valued in reference to current public prices, or, where applicable, using accepted valuation methods), in a *publicly-traded* company that is i) the sponsor of research at the Feinstein, Health System or a Health System owned or controlled entity, or ii) the manufacturer of a product to be studied or tested in research at or under the auspices of the Feinstein, Health System or a Health System owned or controlled entity.
- D. Individuals responsible for institutional purchasing or decision making authority: When a research investigator, business unit administrator, key employee or institutional official participates materially in a procurement or purchasing decision involving major institutional purchases from, or non-routine supply contracts with, a company where the Health System, the Feinstein, or Business Unit will receive significant milestone payments and/or royalties from the purchase.
- E. Gifts: are generally prohibited under health system policy 800.04 Gifts and Interactions with Industry. All charitable donations must be processed through the health system foundation office in compliance with 800.04.
- F. Any significant donation to the Health System foundation from an entity that is i) the sponsor of research at the Feinstein, Health System or a Health System owned or controlled entity, or ii) the manufacturer of a product to be studied or tested in research at or under the auspices of the Feinstein, Health System or a Health System owned or controlled entity.

Reporting

Relationships that warrant disclosure must be reported regularly by the Office of North Shore Ventures, Procurement and Research Administration (e.g. Grants Management Office and the Office of Technology Transfer) to the Office of Research Compliance, who will in turn determine whether formal review is required by the Institutional Conflict of Interest Committee (ICIC).

Institutional conflicts involving key employees, trustees, material amounts or unique cases will be presented to the Health System Audit and Compliance Committee of the Board of Trustees for discussion and concurrence of any proposed management plan.

Review Process

When deemed necessary by the ORC, the Institutional Conflicts of Interest Committee (ICIC) will review and determine whether the interest disclosed represents a conflict of interest. For research related activities, the committee will differentiate between research that is clinical and non-clinical. The potential risks are greater with human subject research and any proposed management plans should be more stringent when a project involves clinical research.

Legal will review terms and conditions of the agreement/contract between the Health System and the external entity in order to ensure that all agreements/contracts are executed at arm's length. The scientific merit of research proposals will be evaluated by the Chief Scientific Officer.

The purpose of the ICIC is:

1. To review the establishment of an entity by any Health System owned or controlled entity that will be engaged in Business or Research Activity;
2. To evaluate any implications for the Health System's 501(c)(3) status;
3. To evaluate the roles and responsibilities of management for the entities; and
4. To evaluate the overall appropriateness of the relationship.

The for Senior VP for Research will appoint a standing committee to review agreements/contracts and to make determinations with respect to the resolution of existing or potential Institutional financial conflicts of interest. Details regarding membership of the ICIC are outlined in the ICIC charter.

Meetings will occur at least annually and on an as needed basis thereafter. No meetings will be held in quarters where there are no disclosures warranting committee review. Subject matter experts may be called to provide input on an ad hoc basis and will not retain voting rights. In addition, members of Health System, Research Administration, North Shore Ventures and Technology Transfer may be called upon to provide input on an ad hoc basis.

Review and Resolutions of Institutional Conflicts of Interest

The ICIC shall make a determination through a majority vote whether, an institutional conflict of interest exists, that is, if the Committee believes that the significant interest disclosed could affect or appear to affect the design, conduct or reporting of any research or educational activities which are the subject of the Research Activities, or may have the opportunity or appear to have

the opportunity to influence research, business, or clinical decisions of the Health System or the Feinstein.

Management Plans for Institutional Conflict of Interest

The ICIC will assess whether there is potential for an institutional conflict of interest concurrent to Health System negotiations pertaining to a commercial transaction that has, or appears to have a significant impact on research, or raises unusual questions of public interest or public policy. The ICIC will consider appropriate management of the conflict.

Non-Human Subjects Research:

The primary reasons to manage Institutional COI in non-human subjects research focus on maintaining objectivity within the Health System's research and educational missions. If a decision is made by the ICIC that the scientific value of the research exceeds the potential risks related to Institutional COI, the ICIC will consider appropriate management of the conflict (e.g. external oversight proportional to the risk to the Health System's reputation and/or mission and required disclosures).

Human Subjects Research:

When a potential institutional COI that involves a human research project is identified, the ORC will notify the IRB and the Grants Management Office (if the institutional COI involves a sponsored project). When a potential institutional COI is identified in a project involving human subjects, the ICIC shall apply a default position that either the financial interest should be eliminated or the human subject research should not be conducted at the institution. The presumption may be rebutted if the circumstances are deemed compelling by the ICIC, and provided that the Committee approves an effective institutional COI management plan. Whether the presumption is successfully rebutted will depend in each case upon an analysis of:

- the nature of the science,
- the nature of the overlapping interests,
- how closely the interest is related to the research,
- the degree to which the interest may be affected by the research,
- the degree of risk that the research poses to human subjects and the integrity of the research, and
- the degree to which the institutional COI can be effectively managed

In deliberations, the ICIC should consider whether the institution is uniquely qualified, by virtue of its attributes (e.g., special facilities or equipment, unique patient population) and the experience and expertise of its investigators, to conduct the research and safeguard the welfare of the human subjects involved. If it is determined that there are compelling circumstances for allowing the research to proceed in the presence of the institutional COI without elimination or significant reduction of the financial interest, this will be documented in the management plan and any subsequent ICIC reports on the matter.

If the ICIC concludes that an institutional conflict does exist but that the human subject project should be allowed to proceed, the ICIC will propose remedies for the management and resolution of actual or potential conflicts.

Management plans for approved institutional COI arrangements will be designed effectively to address: 1) the nature of the conflict; 2) the specific risks to human subjects; 3) the perceived risk to the integrity of the research as a result of the conflict; and 4) the perceived risk to the reputation of the Health System or the Feinstein (as applicable).

Examples of management plans may include one or more of the following:

1. Disclosure of the institutional COI in the informed consent process;
2. Where the institutional COI involves a senior official, formal recusal of the conflicted official from the chain of authority over the project and possibly also from authority over salary, promotion, and space allocation decisions affecting the investigator, as well as communication of the recusal arrangements to the official's superior and colleagues.
3. Where the institutional COI involves a senior official, designation of a "safe haven" (e.g., a non-conflicted senior individual) with whom the investigator can address institutional COI-related concerns;
4. Use of an external Institutional Review Board (since most institutional IRBs are composed of faculty and staff from the institution);
5. External monitoring of the study, particularly endpoint assessments;
6. Use of an external Data Safety Monitoring Board or similar review board to evaluate the design, analytical protocols, and primary and secondary endpoint assessments, and to provide ongoing evaluation of the study for safety, performance issues and the reporting of results;
7. Disclosure of the institutional COI in public presentations and publications;
8. Disclosure of the institutional COI to other centers in a multi-center trial.

Records

The Office of Research Compliance shall maintain records of all disclosures and of all actions taken to resolve actual or potential financial conflicts of interest until at least three (3) years after the later of the termination or completion of the research activities to which they relate, or the resolution of any government action involving those records.

Confidentiality

Disclosures of significant financial interests shall be maintained in a careful and discreet manner and made available within the Health System only to those who have an administrative need to see them.

In addition, the Feinstein or appropriate hospital or entity within the Health System may have an obligation to advise the applicable governmental granting agency or the Department of Health and Human Services with respect to significant financial interests and how they are being managed, reduced, or eliminated to protect the research from bias. A regulatory body or government agency may at any time request submission of, or review on site, all records pertinent to the certification by the Feinstein or appropriate hospital or entity within the Health System in this regard.

Auditing and Monitoring

The Office of Research Compliance or Internal Audit may conduct periodic routine and for cause auditing and monitoring. It is the responsibility of all employees to conduct themselves in compliance with this policy. Employees may report incidents of non-compliance via the Corporate Compliance Help Line 1-800-894-3226 or by web-based reporting at www.northshore-lij.ethicspoint.com.

Non-compliance with this policy will lead to disciplinary action which may include suspension or termination of employment.

REFERENCES to REGULATIONS and/or OTHER RELATED POLICIES

- NSLIJHS Policy 800.03 Conflict of Interest and Recusal
- NSLIJHS Policy 800.04 Gifts and Interactions with Industry
- NSLIJHS Policy GR065 Review and Management of External Interests (COIs) in Research (Individual)
- NSLIJHS Policy 100.024 Policy on Intellectual Property
- NSLIJHS Policy 100.027 Policy on Technological Licensing and Distribution of Royalty Income
- NSLIJHS Policy 300.16 Vendor Screening and Compliance

CLINICAL REFERENCES

N/A

FORMS

N/A

<u>APPROVAL:</u>	
System Administrative P&P Committee	7/25/13 Provisional; 8/29/13Final; 7/30/15
System PICG/Clinical Operations Committee	9/19/13; 9/17/15