North Shore – LIJ Health System, Inc.
Hofstra North Shore-LIJ School of Medicine

POLICY TITLE: **Review and Management of Financial Conflict of Interest in Research (Individuals)**	**ADMINISTRATIVE POLICY AND PROCEDURE MANUAL**
POLICY #: GR065	**CATEGORY: Research**
System Approval Date: 9/19/13 **Site Implementation Date: 9/19/13**	**Effective Date: 6/21/12** **Last Revised/Reviewed: September 2013**
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GENERAL STATEMENT of PURPOSE

Conflict of Interest (COI) or the appearance of a conflict may arise in connection with Research Activities and as a result of a Covered Individual's involvement with outside entities.

The purpose of this policy is to promote the identification, disclosure and, if required, resolution or management of such individual financial Conflicts of Interest (fCOI) in the context of research.

SCOPE

This policy applies to faculty of the Hofstra North Shore-LIJ School of Medicine conducting 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 at North Shore – LIJ Health System.

POLICY

This policy is based on federal guidance and regulation (Department of Health and Human Services, Office for Human Research Protections Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection; **Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is sought (42 CFR Part 50 Subpart F, grants and 45 CFR Part 94, contracts)** and sound management principles.

It is the policy of the Health System that all faculty, students and staff exercise reasonable efforts to avoid conflicts of interest and comply with requirements of federal and state laws and/or regulations governing potential conflicts.

Disclosure to the Institution

Voluntary and timely disclosures of potential conflict of interest by Covered Individuals must be made in order to allow the Hofstra North Shore-LIJ School of Medicine ("School of Medicine") Feinstein Institute for Medical Research ("Institute") or North Shore-LIJ Health System ("Health System") to take any steps required to avoid the substance or appearance of a conflict of interest when Covered Individuals engage in external activities.

Covered Individuals must disclose all Significant Financial Interests (SFI):

1. at least annually,
2. no later than the time of application for PHS funded research, and
3. within 30 days of discovering or acquiring a new SFI

The Institution will then evaluate all disclosed SFIs to determine if any of the interest relates to a covered individual's professional responsibilities and where it is determined that a fCOI exists related to their research implement a management plan within 60 days.

Travel Disclosure to the Institution for Key Personnel on PHS (NIH) funded grants and contracts

As of August 2012 key personnel on PHS funded grants will also be required to disclose the occurrence 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. This disclosure requirement 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.

Travel disclosure, must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Upon receipt of this information, the responsible institutional official or designee will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an fCOI with the PHS-funded research.

Reporting to NIH

Institutions which identify research investigator financial conflicts of interest are required to report the conflicts to the Grants Management Officer at the National Institutes of Health (NIH) Institute or Center which funds or will fund the project. As a result significant financial interests which are determined to be a conflict of interest must be reported by the relevant institutional grants office, the Feinstein/North Shore-LIJ Grants Management Office or the Hofstra University Sponsored Programs Office, to the NIH prior to the expenditure of funds, within 60 days of identification for an investigator who is newly participating in the project, within 60 days for

new or newly identified financial Conflicts of Interest for existing investigators, following a review to update a previously submitted report, and at least annually (for example at the time of progress report submission or a request for an extension). The information to be disclosed will include at a minimum:

- NIH project number;
- Name of Program Director/Principal Investigator or Contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the Financial Conflict of Interest;
- Name of the entity with which the Investigator has a Financial Conflict of Interest;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (dollar ranges are permissible: $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;
- A description of how the financial interest relates to the NIH-funded research and why the Institution determined that the financial interest conflicts with such research;
- A description of the key elements of the Institution's management plan, including:
    - Role and principal duties of the conflicted Investigator in the research project;
    - Conditions of the management plan
    - How the management plan is designed to safeguard objectivity in the research project;
    - Confirmation of the Investigator's agreement to the management plan;
    - How the management plan will be monitored to ensure Investigator compliance; and
    - Other information as needed.

Public Disclosure

Information regarding research investigator financial Conflicts of Interest (fCOI) must also be made available to the public. As a result all significant financial interests held by the senior/key personnel for a NIH-funded research project that are determined to be financial Conflicts of Interest (fCOI) will be made available within five business days to those in the public who have submitted a written request for information concerning any Significant Financial Interest disclosed to the Institution that meets the following three criteria:

- The Significant Financial Interest was disclosed and is still held by the senior/key personnel for the NIH-funded research project identified by the Institution in the grant application, progress report, or any other required report submitted to the NIH;
- The Institution determines that the Significant Financial Interest is related to the NIH-funded research; and
- The Institution determines that the Significant Financial Interest is a **Financial Conflict of Interest.**

The information to be publicly disclosed will include at a minimum:

- Investigator's name;
- Investigator's title and role with respect to the research project;
- Name of the entity in which the Significant Financial Interest is held;
- Nature of the Significant Financial Interest; and
- Approximate dollar value of the Significant Financial Interest (dollar ranges are permissible: $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.

Training

All covered individuals must receiving training prior to engaging in research related to any PHS funded grant, at least every 4 years, and immediately if an institution revises sections of its fCOI policy that affects the requirements of investigators, when an investigator is new to the institution, or when an investigator is non-compliant with this policy or a management plan.

Rules Concerning Other Common Types of Conflict Situations

Apart from conflicts involving significant financial interest or time and commitment, certain other rules must be observed to avoid conflict situations as follows:

- Purchasing for the Institute, the Health System or the School of Medicine - Purchase of goods or services for the Health System's, Institute's, of School of Medicine's purposes from an organization in which you have significant financial interest is prohibited without prior disclosure and approval.
- Cash – No cash or cash equivalents may be accepted from outside organizations with which the School of Medicine, Institute or the Health System does or may conduct business.
- Gifts and Gratuities - Gifts or gratuities from outside organizations with which the School of Medicine, Institute or the Health System does or may conduct business are not to be accepted.
- Confidentiality - Acceptance of outside employment or engaging in any outside business, consulting arrangement or external activity which would require disclosure of confidential information acquired by reason of the Covered Individual's position at the School of Medicine, Institute or within the Health System is a violation of this policy.
- Speaker's Bureaus: Individuals are prohibited from participating in Industry-sponsored Speaker's Bureaus unless academic investigators are presenting results of their research to peers and there is an opportunity for critical exchange; Likewise individuals are prohibited from receiving compensation for listening to a sales pitch (e.g., detailing) by an Industry representative.

Conflicts of Commitment

Covered Individuals are expected to devote their primary professional loyalty, time, and energy to, as applicable, their teaching, research, patient care, and service. Outside activities must be arranged so as not to interfere with the primacy of these commitments. In keeping with this policy, it is the practice of the Institute and the Health System to permit Covered Individuals to devote an average of up to one day per week toward external activities, provided that the

Covered Individual's work for the Institute, hospital or other entity within the Health System is not affected adversely and has received appropriate institutional approvals.

General Principles Concerning Consulting and External Activities

In keeping with Gifts and Interactions with Industry Policy 800.04 acceptance of any Industry honoraria or consultation engagement is contingent on the prior approval from an appropriate Administrative Director, Chairperson, or similar position. A Chairperson needs approval from the Chief Medical Officer. Presentations or consultation engagements must be of scientific/academic merit and/or benefit the Institute, Health System or the School of Medicine.

Principal Investigators and other senior/key personnel must also adhere to the separate policy Review of External Consulting Agreements with Industry, GR078, prior to engaging in an outside consulting relationship. Note neither the Institute nor any hospital or entity within the Health System will be a party to the private consulting contracts of any Covered Individual.

Commercial Sponsorship of Investigator Initiated Research

Neither the Institute nor any hospital or facility within the Health System will be a signatory party to any grant or contract which obligates a Covered Individual to provide private consulting services to outside entities. However, a sponsor of research may negotiate independent contracts for extramural research with a Covered Individual working on a sponsored research project. To avert inherent or latent conflicts of interest in such contracts, a separate sponsored research agreement must be drafted and presented to the Office of Technology Transfer or the Grants Management Office and, if necessary, the Conflicts Committee, for review and approval.

Intellectual Property

Intellectual property related to professional activities must be disclosed to the institution as a significant financial interest. Note the Health System and the Institute has a separate Policy GR017 Intellectual Property which covers the development, use and exploitation of intellectual property conceived or reduced to practice by Covered Individuals. Under the IP Policy, the Institute is responsible for all matters concerning intellectual property generated by owned hospitals and entities within the Health System. Provided the specified connections with the Health System or the Institute exist, the Health System and the Institute may have rights with respect to such intellectual property referred to in the IP Policy. The existence of such preemptive rights should be considered by Covered Individuals before rendering or agreeing to render consulting services. Covered Individuals should disclose, in advance, the existence of these rights to the parties with whom consulting arrangements are to be made. This helps to ensure that consulting contracts acknowledge the policies and rights of the Health System and the Institute. In general, Covered Individuals should consult with the Office of Legal Affairs, in advance, to resolve any potential problems with intellectual property-related issues arising from consulting agreements. This may be done informally through the Senior Vice President and General Counsel or his designee, who can advise about circumstances typically encountered in consulting arrangements.

This policy cannot set out every possible situation that is potentially a conflict situation. When a question as to the existence of a real or potential conflict of interest arises, it is important that the Covered Individual consult with the Responsible Institutional Official. If necessary, the

Responsible Institutional Official will present the facts of the situation to the Conflicts Committee for resolution.

PROCEDURE/GUIDELINES

Individual Responsibilities

Every Covered Individual is required to complete a Significant Financial Interest Questionnaire Annual Disclosure) at least once a year. In addition every Covered Individual is required to provide updates as changes are made and at the time of any grant application, submission to the Institutional Review Board, submission to the Institutional Animal Care and Use Committee, appointment to the IRB, IBC, IACUC, Intellectual Property, or Conflict of Interest Committee or, at the time of entering into any sponsored research agreement or consulting agreement indicating whether there have been any changes to his/her annual disclosure (Updated Disclosure).

- All completed Annual Significant Financial Interest Questionnaires will be submitted to the Office of Research Compliance, Questionnaires which make a disclosure of a significant financial interest shall be delivered to the Responsible Institutional Official or designee for review.
- All Updated disclosure forms will be submitted to the Office of Grants and Contracts, and IRB, IBC, COI Committee, or IP Committee, if applicable. Updated disclosures which indicate a significant financial interest that had not been previously reported or which had changed from the prior disclosure shall be delivered to the Responsible Institutional Official or designee for review.

Review and Resolutions of Conflicts of Interest

It is important to note that covered individuals must disclose all interests which meet the definition of a Significant Financial Interest. However, the disclosure of a Significant Financial Interest does not automatically mean that a Financial Conflict of Interest (fCOI) exists.

A Financial Conflict of Interest (fCOI) exists if the significant financial interest disclosed could affect or appear to affect the design, conduct or reporting of the research or educational activities which are the subject of the Research Activities.

The Responsible Institutional Official or designee shall make a determination whether, in his or her opinion, a potential financial Conflict of Interest (fCOI) exists and if so whether the potential fCOI can be may reviewed via expedited review or requires the review of the COI Committee.
Under an expedited procedure, review is carried out by the Chair of the COI Committee (COIC) or another member of the COIC without a convened meeting of the full committee. After the review has been completed, the Office of Research Compliance will send written correspondence to the covered individual with one of the following decisions, along with additional comments where appropriate.

1. Review has been completed, disclosure is sufficient, no fCOI has been identified and no further action is required
2. Review has been completed, it has been determined that a minor fCOI exists, a management plan with investigator concurrence is required

3. Review is pending, additional information is required
4. A potential significant fCOI has been identified and has been escalated to the COIC.

Note the designated reviewer may request any aspect of a management plan to be implemented with the exception of divestiture of the significant financial interest. Only a majority vote of the full COIC may determine that a covered individual must divest their significant financial interest as part of a management plan.

If the Responsible Institutional Official or designee and/or the designated expedited reviewer conclude that a potential fCOI exists requiring full board review, he or she shall so inform the Covered Individual and submit the matter to the Conflicts Committee which may concur or disagree with the Responsible Institutional Official's determination.

Communication and Implementation of Management Decisions

When it is determined that a financial Conflict of Interest (fCOI) exists the designated reviewer and/or the COIC will propose remedies to reduce, manage, or eliminate actual or potential fCOI revealed. Remedies are based on the severity of the potential conflict of interest, level of risk of the study, and potential for the involvement of human subjects. Examples include but may not be limited to:

- Disclosure (oral and written) to research subjects during the informed consent process
- Disclosure to co-investigators, collaborators, or study sponsors
- Restrictions on an individual's ability to recruit or obtain informed consent from prospective subjects
- Third party monitoring of the conduct of the study
- Restrictions on data management and analysis
- Disclosure in publications and presentations
- Divestiture of the interest
- Restrictions on the ability to conduct the study at this institution

The Covered Individual will be required to confirm receipt of the decision and concurrence with the management plan in all cases where a management plan is required.

Determinations made by the Responsible Institutional Official or Conflicts Committee shall be communicated in writing to the Covered Individual, the Grants Management Office, Corporate Compliance, IRB or IACUC, as applicable, by the Responsible Institutional Official or designee. Covered Individuals who fail to promptly comply with the decisions of the Conflicts Committee in resolving or waiving conflicts of interest may be subject to employment sanctions by the Institute or the applicable hospital or entity within the Health System, as the case may be.

Notwithstanding the foregoing, the Covered Individual may request a reconsideration by the Conflicts Committee of its determination and, if the Conflicts Committee then determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress or the public health and welfare, the Conflicts of Interest

Committee will so note such fact and, if not otherwise prohibited by law or regulation, may allow the research to go forward without imposing such conditions or restrictions.

All financial Conflicts of Interest disclosed under this policy, if not clearly resolvable based on the guidelines set forth, will be referred to the Office of Legal Affairs for resolution.

Conflict of Interest Committee (COIC) Membership

The Senior Vice President for Research will appoint a standing committee to review disclosures and to make determinations with respect to the resolution or waiver of existing or potential financial Conflicts of Interest and such other ad hoc committees as are deemed appropriate to implement this Conflicts Policy. At a minimum, members of any committee constituted pursuant to this Section shall include a representative from the Office of Legal Affairs, a representative from the Grants Management Office, the Responsible Institutional Official, the Chief Scientific Officer of the Institute, a representative from Corporate Compliance, a representative from Research Compliance, a Senior Faculty Practice Representative, a representative from Procurement, a representative from Human Resources, a representative from the Office of the Chief Information Officer and at least two Covered Individuals.

Members of the Conflicts Committee will serve indefinable terms but must attend at least 50% of all convened meetings in a 12 month period to be considered members in good standing. Members who attend less than 50% of convened meetings will be evaluated for potential replacement.

Records

The Responsible Institutional Official or designee 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 Activity 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. However, the Institute or appropriate hospital or entity within the Health System has 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. As a result significant financial interests which are determined to represent a conflict of interest will be reported to federal granting agencies and the Food and Drug Administration if applicable.

The Institute will also provide information to the public in compliance with federal regulations on Promoting Objectivity in Research when significant financial interests have been determined to be conflicts of interest.

The Institute and all hospitals or entities within the Health System also have a responsibility to keep the applicable granting agency fully informed if they are unable to satisfactorily manage an actual or potential financial conflict of interest. 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 Institute or appropriate hospital or entity within the Health System in this regard.

Auditing and Monitoring

The Office of Research Compliance, Corporate Compliance, or Internal Audit will conduct periodic routine and for cause 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.

DEFINITIONS

"**Covered Individuals"** shall mean all individuals (salaried and non-salaried), including employed physicians, voluntary physicians, residents, departmental heads, administrators and members of the faculty of the Institute or any owned hospital or entity within the Health System and related parties who are engaged or proposing to engage in Research Activities at or on behalf of the School of Medicine, the Institute, or the Health System.

"**Conflicts of Commitment**" is a type of conflict of interest where the Covered Individual's service to or activities with an outside organization interferes or has the appearance of interfering with the commitment, loyalty and time such Covered Individual reasonably needs to devote in order to fully conduct his or her work at the Institute or for the hospital or entity within the Health System that employs such individual.

"Financial Conflicts of Interest (FCOI)" include significant financial interests which could directly and significantly affect the design, conduct or reporting of Research Activities. Financial Conflicts of Interest also involve situations in which an individual may have the opportunity or appear to have the opportunity to influence the Health System's or Institute's decisions or to use the resources or proprietary information of the Health System in ways that could lead to gain or advantage to the Covered Individual and related party or any organization in which such Covered Individual and related party may have a significant financial interest.

"Disclosure" means the provision of information about significant financial interests and consulting or external activities in connection with professional activities.

"Entity" means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or in which any person has an ownership or equity interest. For example this includes but is not limited to foundations, professional organizations, pharmaceutical companies, and device manufacturers. It does not include federal agencies.

"Institutional Animal Care and Use Committee or IACUC" means any board, committee, or other group formally designated by the Institute or any hospital or entity within the Health System to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving animals. The primary purpose of such review is to assure the ethical treatment of animals used in research.

"Institutional Review Board or IRB" means any board, committee, or other group formally designated by the Institute or any hospital or entity within the Health System to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects.

"Owned hospital or entity" shall mean any hospital that has the North Shore Health System as its sole corporate parent and shares a common board of directors and management with the Health System.

"Professional Responsibilities" shall mean activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

"Related Party" shall mean spouse, domestic partner, & dependent children.

"Research Activity(ies)" means 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.

"Responsible Institutional Official" means the individual designated by the CEO of Health System, as responsible for oversight of Research Activities.

"Significant Financial Interest" includes:

(i) the value of any remuneration received from an external entity (including Consulting fees, honoraria, gifts or other emoluments, or "in kind" compensation), whether for consulting, lecturing, travel, service on an advisory board, or for any other purpose not directly related to the reasonable costs of conducting the Research Activity (as specified in a research agreement between the sponsor and the Institute) in the twelve months preceding the 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);

(ii) the value of any equity interest in a publicly traded entity as of the date of disclosure, when aggregated, exceeds $5,000; 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;

(iii) Equity interests, including stock options, of any amount in a non-publicly-traded company (or entitlement to the same) 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

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

(v) Service as an officer, director, or in any other fiduciary role for an entity, whether or not remuneration is received for such service.

Exceptions. Significant financial interest does not include the following:

- Interests of any amount in publicly traded, diversified mutual funds as long as the Investigator does not directly control the investment decisions made in these vehicles.
- Stock in a publicly-traded company that (when valued in reference to current public prices) does not exceed $5,000.
- Stock options in a publicly-traded company that (when valued using accepted valuation methods) does not exceed $5,000.
- Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization
- Payment to the Institute, or via the Institute to the individual, that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement(s) between the sponsor and the Institute.
- Salary and other payments for services from the Institute or any hospital or entity within the Health System.
- 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; or
- 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.

REFERENCES to REGULATIONS and/or OTHER RELATED POLICIES

- 42 CFR Part 50 Subpart F
- 45 CFR Part 94
- NSLIJHS Policy GR078 – Review of External Consulting Agreements with Industry
- NSLIJHS Policy GR017 – Intellectual Property

CLINICAL REFERENCES
N/A

APPROVAL:	
System Administrative P&P Committee	5/31/12; Provisional Approval 7/25/13; 8/29/13
System PICG Committee/Clinical Operations Committee	6/21/12; 9/19/13

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