Northwell Health

POLICY TITLE: Review and Management of External Interests (COIs) in Research (Individuals)	**ADMINISTRATIVE POLICY AND PROCEDURE MANUAL**
POLICY #: GR065	**CATEGORY:** Research
System Approval Date: 4/21/16 **Site Implementation Date:** 6/3/16	**Effective Date:** 6/21/12 **Last Reviewed/ Revised:** 11/20/14
Prepared by: Office of Research Compliance Emmelyn Kim, Scott Beardsley	**Superseded Policy(s)/#:** N/A

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 an Investigator'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 COI in an effort to promote objectivity and alleviate the potential for real or perceived bias in the context of research.

POLICY

This policy is based on federal guidance and regulation from the 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; and 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 Northwell Health 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, and institutional policy governing potential conflicts.

Individuals are required to adhere to other applicable institutional policies related to reducing and managing conflicts of interest that govern professional and business interactions or transactions. Refer to Corporate Compliance Policies including 800.03 Conflict of Interest and Recusal and 800.04 Gifts and Interactions with Industry for more information. Disclosures may require review by the Office of Corporate Compliance.

Disclosure to the Institution

Voluntary and timely disclosures of External Interests for individuals (and related parties) involved in the design, conduct or reporting of research and participating as members of an

institutional research committee (where required) must be submitted for review in order to allow the Hofstra North Shore-LIJ School of Medicine ("School of Medicine"), Feinstein Institute for Medical Research ("Institute"), or Northwell Health to take any steps required to avoid the substance or appearance of a conflict of interest when individuals engage in external activities. Phase I Small Business Innovative Research (SBIR)/Small Business Technology Transfer (STTR) applicants are not required to disclose external interests to the institution.

Individuals must disclose External Interests:

1. At least annually when research is ongoing or anticipated;
2. No later than the time of application for Public Health Service (PHS) funded research; ***and***
3. Within 30 days of discovering or acquiring a new Significant Financial Interest (SFI). A new SFI is a different type or nature of SFI (e.g., royalty payment versus consulting fees) than what had previously been disclosed from the same source that meets or exceeds the threshold. In addition, a "new" SFI is also considered to be the same type or nature of SFI (e.g., royalty payment) from a different source (e.g., company A versus company B).

The Institution will then evaluate all disclosed SFIs to determine if any interests relate to an individual's professional responsibilities Where it is determined that a potential or actual COI exists related to their research, the Institution will implement a management plan for the individual in an effort to eliminate or mitigate the COI in the context of the research.

Requirements for PHS (e.g. NIH) Funded Grants and Contracts

1. Key personnel on PHS funded grants will be required to disclose reimbursed or sponsored travel.
2. Significant financial interests determined to be a conflict of interest must be reported by the relevant institutional grants office to NIH.
3. Information regarding investigator conflict of interests must be made available to the public.
4. Other funding agency COI requirements must be followed.

Training

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

Non-compliance with this policy may lead to disciplinary actions, which may include suspension or termination of research activities or involvement in research. Federal Institutions may impose special conditions on a grant to allow the grantee to take corrective action; if a grantee has failed to materially comply with the terms and conditions of award, a federal institution may take action to wholly or partly suspend the grant, pending corrective action, or may terminate the grant.

SCOPE

This policy applies to all members of the Northwell Health workforce including, but not limited to: employees, medical staff, volunteers, students, physician office staff, and other persons performing work for or at Northwell Health; faculty and students of the Hofstra Northwell School of Medicine conducting Research on behalf of the School of Medicine on or at any Northwell Health facility; and the faculty and students of the Hofstra Northwell School of Graduate Nursing & Physician Assistant Studies.

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 Northwell Health 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 Northwell Health.

"**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 Northwell Health that employs such individual.

"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.

"Investigator" is defined to encompass individuals responsible for the design, conduct or reporting of research.

"IACUC" – The Institutional Animal Care and Use Committee**,** is responsible for the assessment and oversight of the institution's entire Program, its components and facilities. The primary purpose of such review is to assure the ethical treatment of animals used in research.

"Institutional Review Board (IRB)" A committee constituted in compliance with DHHS regulations at 45CFR46 and FDA regulations at 21CFR50 that has been formally designated by an institution to review and monitor biomedical and behavioral research involving human subjects. In accordance with regulations, an IRB has the authority to approve, require modifications in, or disapprove research. The purpose of IRB review is to ensure, both in advance and by periodic continuing review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research. To accomplish this purpose,

IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.

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

"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 Activities" 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 Northwell Health, as responsible for oversight of Research Activities.

"Significant Financial Interest" includes a financial interest consisting of one or more of the following interests of the Investigator (and related parties such as spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities: With regard to any publicly traded entity, a 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;

With regard to any non-publicly traded entity, a 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 Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

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 determined to be an SFI;

- **Exceptions.** The term "**significant financial interest"** does not include the following:
  - Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
  - Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
  - 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;
  - 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.

PROCEDURE/GUIDELINES

Individual Responsibilities

An up-to-date external disclosure form must be on file with the Office of Research Compliance (ORC) at the time of submission of any grant application to the Grants Management Office (GMO), submission to the Institutional Review Board (IRB) the Institutional Animal Care and Use Committee (IACUC), and appointment to any institutional research committees (e.g. IRB, RDRC, IBC, IACUC, or Conflict of Interest Committee), and at the time of entering into any sponsored research agreement or consulting agreement.

All completed External Interest Disclosure Forms will be submitted to the ORC for review. In addition every individual is required to provide updates, within 30 days of discovery or acquisition of new reportable financial interests. All updated external disclosure forms will be available for review by the ORC, GMO, IRB, IACUC, Office of Technology Transfer (OTT), Institutional Biosafety Committee (IBC), and COI Committee.

Review and Resolution of Conflicts of Interest

It is important to note that individuals must disclose all interests that 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 exists. A financial Conflict of Interest 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.

Role-based Conflicts: Individuals are evaluated if they serve as an officer, director or in any other fiduciary role for an entity, whether or not remuneration is received for such service.

Individuals are also evaluated if they have a research study leadership role (e.g. Global or National PI or serves on an Executive Committee/Steering Committee) or sit on a Data Safety Monitoring Committee and receive confidential information regarding the research trial. Such individuals are generally restricted from serving as the local PI in Northwell Health or as an enrolling investigator. See the Global/National PI and Study Leadership COI Guidance for more information.

Financial Conflicts of Interest also involve situations in which an individual may have the opportunity or appear to have the opportunity to influence Northwell Health's or Institute's decisions or to use the resources or proprietary information of Northwell Health in ways that could lead to gain or advantage for the individual and related party or any organization in which such individual and related party may have a significant financial interest.

The Responsible Institutional Official or designee within the ORC shall make a determination whether, in his or her opinion, a potential financial COI exists and if so, whether the potential COI may be reviewed via expedited procedures or requires the review of the COI Committee. Expedited, review procedures are carried out by a designated member of the ORC.

The ORC will notify the individual of the following, as applicable, along with additional commentary where appropriate:

- Review has been completed and the disclosure is sufficient; no SFIs or COIs have been identified and no further action is required.
- Review has been completed, it has been determined that an SFI and potential or actual COI exists; a management plan with investigator concurrence is required.
- Review is pending, additional information is required
- An SFI and potentially significant COI has been identified and has been escalated to the COIC for review.

Remedies are based on the severity of the potential COI, level of risk of affected studies, 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
- Disclosure to the Office of Procurement when purchasing products or services
- Restrictions on an investigator'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

Note the designated reviewer may require any aspect of a management plan with the exception of divestiture of the significant financial interest. Only a majority concurrence of the full COIC may determine that an individual must divest their significant financial interest as part of a management plan.

If the research involves human subject research, the IRB has the final authority to decide whether the interest and its management, if any, allows the research to be approved.

Management Plans

The 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. If the individual disputes the terms and conditions of a management plan the case will be referred to the COI Committee for resolution. If the COI Committee 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 COI 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 COIs 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. Determinations made by the Responsible Institutional Official, designee or COI Committee shall be communicated to the individual, and will be available for review by the following: the GMO, Corporate Compliance, IRB or IACUC, and other offices when applicable. Individuals who fail to promptly comply with the decisions of the COI Committee in resolving conflicts of interest may be subject to employment sanctions by the Institute or the applicable hospital or entity within Northwell Health, as the case may be.

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 of existing or potential financial Conflicts of Interest and such other ad hoc committees as are deemed appropriate to implement this policy. Details regarding membership of the COIC are outlined in the COIC charter.

Conflicts of Commitment

Investigators 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 Northwell Health 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 Northwell Health 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, Northwell Health or the School of Medicine. Individuals are also 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.

Principal Investigators and other research personnel must also adhere to the separate policy GR078 Review of External Consulting Agreements with Industry for Researchers prior to engaging in an outside consulting relationship. Note neither the Institute nor any hospital or entity within Northwell Health 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 Northwell Health 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 (see policy 100.007 Signatory Authority for Grants Administration).

Intellectual Property

Intellectual property related to professional activities that is conceived or reduced to practice by the investigator and results in royalty payments must be reported on external disclosure forms submitted for evaluation by the ORC. Note Northwell Health and the Institute have a separate Intellectual Property policy, 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 Northwell Health. Provided the specified connections with Northwell Health or the Institute exist, Northwell Health 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 Northwell Health 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 or designee. If necessary, the Responsible Institutional Official or designee will present the facts of the situation to the COI Committee for resolution.

Travel Disclosure to the Institution for Investigators on PHS Funded Grants and Contracts

Investigators involved in the design, conduct, or reporting of research on PHS funded grants are required to disclose the occurrence of any free-of-charge or discounted travel sponsored by external entities (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.

At a minimum, information disclosed must include the purpose of the trip, the identity of the sponsor, destination and duration of the trip. Additional information may be requested by the reviewer to determine whether travel constitutes a conflict.

Reporting to NIH

Institutions which identify COIs for investigators on PHS funded or supported research are required to report the conflicts to the Grants Management Officer at the National Institutes of Health (NIH), or other PHS 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 fCOI.

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.

Confidentiality

Disclosures of significant financial interests shall be maintained in a careful and discreet manner. However, the Institute or appropriate hospital or entity within Northwell Health 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, the Food and Drug Administration and other parties as applicable.

The Institute and all hospitals or entities within Northwell Health 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 Northwell Health in this regard.

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.

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.

Auditing and Monitoring

The Office of Research Compliance or Internal Audit may 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 may lead to disciplinary action, up to and including termination of employment.

REFERENCES to REGULATIONS and/or OTHER RELATED POLICIES

- 42 CFR Part 50 Subpart F
- 45 CFR Part 94
- GR078 Review of External Consulting Agreements with Industry for Researchers
- 100.024 Intellectual Property
- 100.007 Signatory Authority for Grants Administration
- 800.03 Conflict of Interest and Recusal
- 800.04 Gifts and Interactions with Industry
- Northwell Health Human Resources Policy and Procedure Manual: Conflict of Interest/Gratuities, Part IX, Section 5.
- Global/National PI and Study Leadership COI Guidance

CLINICAL REFERENCES

N/A

FORMS

N/A

ATTACHMENTS

Office of Research Compliance (ORC) Guidance Document

APPROVAL:	
System Administrative P&P Committee	5/31/12; Provisional Approval 7/25/13; 8/29/13; 10/30/14; 3/31/16
System PICG/Clinical Operations Committee	6/21/12; 9/19/13; 11/20/14; 4/21/16

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