



POLICY TITLE: Review and Management of External Interests (COIs) in Research (Individuals)	SYSTEM POLICY AND PROCEDURE MANUAL
POLICY #: GR065	CATEGORY: Research
System Approval Date: 10/18/2018	Effective Date: 06/2012
Site Implementation Date: 11/28/2018	Last Reviewed/Approved: 04/2016
Prepared by: Office of Research Compliance	Notations: 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 COIs 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 COIs 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 (including subrecipients relying on Northwell's COI policy) 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 Zucker 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 COI when individuals engage in external activities. Foreign financial interests including foreign institutions of higher education or the government of another country (which includes local, provincial or equivalent) must be reported.

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).

Individuals are highly encouraged to consult the Office of Research Compliance (ORC) prior to engaging in activities that may pose a potential COI in relationship to their professional responsibilities and/or organizational role.

The ORC (as the designated institutional office) 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. SFIs determined to be a COI must be reported by the relevant institutional grants office to the PHS Awarding Component.
3. Information regarding investigator COIs must be made available to the public.
4. Other funding agency COI requirements must be followed.

COI in Research Training

All researchers must receive COI training through the CITI Program prior to engaging in research, 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

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.

Any SFIs not disclosed timely by an Investigator or previously reviewed by the Institution will be reviewed by the ORC and a management plan put forth as appropriate within 60 days. In accordance with PHS requirements, retrospective reviews will be conducted within 120 days of the Institution's determination of noncompliance for SFIs not disclosed timely or previously reviewed or whenever a financial COI is not identified or managed in a timely manner, which will be documented as required by regulatory requirements.

SCOPE

This policy applies to all Northwell Health employees, as well as medical staff, volunteers, students, trainees, physician office staff, contractors, trustees and other persons performing work for or at Northwell Health; faculty and students of the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell conducting research on behalf of the Zucker School of Medicine on or at any Northwell Health facility; and the faculty and students of the Hofstra Northwell School of Graduate Nursing and 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 Zucker 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 within the U.S.

“Financial Conflict of Interest” means a significant financial interest that could directly or significantly affect the design, conduct or reporting of research or educational activities which are the subject of the Research Activities.

“Investigator” (or Researcher) is defined to encompass individuals responsible for the design, conduct or reporting of research on behalf of the institution.

“IACUC” is a self-regulating entity according to NIH Public Health Service (PHS) Policy and U.S. federal laws must be established by institutions that use laboratory animals for research, teaching or instructional purposes to oversee and evaluate all aspects of the institution’s Animal Research Program. Each local IACUC is responsible for the review and approval of research protocols involving animals and conduct evaluations of the institution's laboratory animal care and use program including inspections of facilities that are required by law to assure the ethical treatment and use of animals in research activities.

“Institutional Review Board (IRB)” is 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.

“Public Health Service (PHS) Awarding Component” shall mean agencies within the U.S. Department of Health and Human Services funding the research, which can include: Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (HIS), National Institutes of Health (NIH) including all institutes within NIH, and Substance Abuse and Mental Health Services Administration (SAMHSA).

“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 (SFI)” 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 in the U.S.; 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 in the U.S..

Note: this exception does not apply to financial interests received from a foreign institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country).

PROCEDURE

Individual Responsibilities

An up-to-date external disclosure must be completed electronically, reviewed by the ORC with management plans (when applicable) issued and accepted by the researcher 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), or Employee Owned Entity (EOE) Committee and appointment to any institutional research committees (e.g., IRB, RDRC, Institutional Biosafety Committee (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 significant and reportable financial interests. All updated external disclosure forms will be available for review by the ORC and administrative offices or committees (e.g., GMO, IRB, IACUC, Office of Technology Transfer (OTT), IBC, and COI Committee).

Role-based or Interest-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. Financial COIs 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 SFI. This includes the following scenarios, which warrant disclosure and review:

- Employees or institutional officials who are authorized to take actions on behalf of the institution and are engaged in research activities in which they or the institution may have a financial interest, which may require review through the Institutional COI process (see policy #800.70 Review and Management of Institutional Financial COI); Individuals that 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).

- Employee owned entities (that may seek to license Northwell Health inventions) and propose research work or involve sub-contracted work through the Small Business Innovative Research (SBIR) or Small Business Technology Transfer (STTR) award mechanisms with the organization (see policy #100.026 on Employee-Owned Entities).
- Employees seeking to invest in non-publicly traded companies where research involving such companies are proposed at the organization. This includes non-publicly traded companies where Northwell Health holds either an existing or Prospective Financial Interest.

Review and Resolution of Conflicts of Interest

It is important to note that individuals must disclose all interests that meet the definition of a SFI. However, the disclosure of a SFI does not automatically mean that a financial COI exists. A financial COI exists if the SFI 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 has designated the ORC to evaluate whether a potential financial COI exists and if so, whether the potential COI may be reviewed via expedited procedures by the ORC or requires the review of the COI Committee (COIC).

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 SFI. Only a majority concurrence of the full COIC may determine that an individual must divest their SFI 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 COIC for resolution. If the COIC determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a SFI are outweighed by interests of scientific progress or the public health and welfare, the COIC 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 ORC or COIC shall be communicated to the individual, and will be available for review by Corporate Compliance and other administrative offices or committees when applicable. Individuals who fail to promptly comply with the decisions of the COIC 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 Executive Vice President for Research (as the Responsible Institutional Official for research) will appoint a standing committee to review disclosures and to make determinations with respect to the resolution of existing or potential financial COI and such other ad hoc committees as are deemed appropriate to implement this policy. Details regarding membership of the COIC are outlined in the charter.

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 Zucker 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.

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. Such activities should be reviewed and approved by their supervisor and/or department chair.

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 COIs 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 #100.024, 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 Executive Vice President and General Counsel or 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 COI arises, it is important that the Covered

Individual consult with the ORC. If necessary, the ORC will present the facts of the situation to the COIC 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 within the U.S. 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 in the U.S.

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 PHS Awarding Component (e.g., 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 PHS Institute or Center which funds or will fund the project. As a result SFIs which are determined to be a COI must be reported by the relevant institutional grants office, the Northwell Grants Management Office or the Zucker School of Medicine Sponsored Programs Office, to the PHS Awarding Component and its subrecipients, if applicable, 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 COI 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:

- PHS/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 COI;
- Name of the entity with which the Investigator has a Financial COI;
- 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 PHS/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.

Prompt reporting to the PHS Awarding Component is required if bias is found with the design, conduct or reporting of PHS funded research (including a mitigation report in accordance with regulations) or if an investigator fails to comply with the institutional COI policy or management plan appears to have biased the design, conduct or reporting of the research. In such cases, disclosure of the financial COI in public presentations of the results of the research, addendums to previously published presentation and any other institutional actions deemed appropriate shall be required.

Public Disclosure

Information regarding research investigator financial COIs must also be made available to the public. As a result all SFIs held by the senior/key personnel for a PHS-funded research project that are determined to be financial COIs will be made available within five business days to those in the public who have submitted a written request for information concerning any SFI disclosed to the Institution that meets the following three criteria:

The SFI was disclosed and is still held by the senior/key personnel for the PHS-funded research project identified by the Institution in the grant application, progress report, or any other required report submitted to PHS awarding component; the Institution determines that the SFI is related to the PHS- funded research; and the Institution determines that the SFI is a financial COI.

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 SFI is held;
- Nature of the SFI; and
- Approximate dollar value of the SFI (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 SFIs 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 SFIs and how they are being managed, reduced, or eliminated to protect the research

from bias. As a result SFIs which are determined to represent a COI 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 COI. 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 SFIs have been determined to be a COI.

Records

The ORC shall maintain records of all disclosures and of all actions taken to resolve actual or potential financial COIs 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.northwell.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
- 800.70 Review and Management of Institutional Financial Conflict of Interest
- 100.024 Policy on Intellectual Property
- 100.007 Signatory Authority for Grants Administration
- 800.03 Conflict of Interest and Recusal
- 800.04 Gifts and Interactions with Industry
- 100.026 Policy on Employee Owned Entities
- Northwell Health Human Resources Policy and Procedure Manual: Conflict of Interest/Gratuities, Part 9-5.
- Global/National PI and Study Leadership COI Guidance

CLINICAL REFERENCES/PROFESSIONAL SOCIETY GUIDELINES

N/A

ATTACHMENTS

N/A

FORMS

N/A

APPROVAL:	
Northwell Health Policy Committee	09/20/2018
System PICG/Clinical Operations Committee	10/18/2018

Standardized Versioning History:

*=Policy Committee Approval; ** =PICG/Clinical Operations Committee Approval

*05/31/12 **06/12/12

*07/25/13 – Provisional

*08/29/13 **09/19/13

*10/30/14 **11/20/14

*03/31/16 **04/21/16

*09/20/18 **10/18/18