



POLICY/GUIDELINE TITLE: Review and Management of Institutional Financial Conflict of Interest	ADMINISTRATIVE POLICY AND PROCEDURE MANUAL
POLICY #: 800.70	CATEGORY: Compliance and Ethics
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Prepared by: The Office of Corporate Compliance	Notations: Formerly GR082

GENERAL STATEMENT of PURPOSE

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

The process for evaluation of *individual* conflicts of interest is currently addressed by Northwell Health through policies #800.03 Conflict of Interest and Recusal and #GR065 Review and Management of External Interests (COIs) in Research (Individual).

POLICY

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

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

Voluntary and timely disclosures of potential conflicts of interest must be made in order to allow the Feinstein or Northwell Health to take steps to avoid the substance or appearance of an institutional COI. Whenever a question as to the existence of an institutional COI arises, it is important that individuals or entities consult with the Office of Corporate Compliance.

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

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

Disclosure: The provision of information about financial or fiduciary interests held by Northwell Health or by Institutional Officials.

Northwell Health Owned or Controlled entity: Any hospital or entity within Northwell Health or an entity owned or controlled by Northwell Health as its sole corporate parent, or is otherwise controlled by Northwell Health or an entity owned or controlled by Northwell Health.

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

Family: (1) his or her spouse, or domestic partner; (2) his or her ancestors, brothers and sisters (whether whole or half-blood), children (whether natural or adopted), grandchildren, great-grandchildren; (3) the spouse or domestic partner of his or her brothers, sisters, children, grandchildren, and great-grandchildren; or (4) any other person if that person resides in the same household as the individual at issue.

PROCEDURE/GUIDELINES

Identification of Potential Institutional Conflicts of Interest (COI)

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

- A. Royalties that may result from licensing, technology transfer, or patents: institutional COI may be present when the institution has the potential to receive significant milestone payments and/or royalties from the sale of a product.
- B. Non-publicly traded equity:
 - a. When, through its technology licensing activities or investments, the institution has obtained an equity interest or an entitlement to equity of any value (including options or warrants or as a result of startup ventures) in a *non-publicly traded* company that is i) the sponsor of research at the Feinstein, Northwell Health or a Northwell Health owned or controlled entity, or ii) the manufacturer of a product to be studied or tested in research at or under the auspices of the Feinstein, Northwell Health or a Northwell Health owned or controlled entity.
 - b. Where Northwell Health employees, trustees and institutional officials, or a member of their Family, invests in or holds board or officer positions in a non-publicly traded company in which Northwell Health has any financial interest.
- C. Publicly traded equity: When, through technology licensing activities or investments related to such activities, the institution has obtained an ownership interest or an entitlement to equity (including options or warrants), in a *publicly-traded* company that is i) the sponsor of research at the Feinstein, Northwell Health or a Northwell Health owned or controlled entity, or ii) the manufacturer of a product to be studied or tested in research at or under the auspices of the Feinstein, Northwell Health or a Northwell Health owned or controlled entity, (or) iii) where Northwell Health employees, trustees and institutional officials, or a member of their Family hold board or officer positions of the publicly traded company.
- D. Individuals acting on behalf of the institution, responsible for institutional purchasing or decision making authority: When a research investigator, business unit administrator, key employee or institutional official participates materially in a procurement or purchasing decision involving major institutional purchases from, or non-routine supply contracts with, a company sponsoring research or where the Northwell Health, the Feinstein, or Business Unit will receive significant milestone payments and/or royalties from the purchase.
- E. Gifts: are generally prohibited under Northwell Health administrative policy 800.04 Gifts and Interactions with Industry. All charitable donations must be processed through the Northwell Health Foundation Office in compliance with policy 800.04.

- F. Any significant donation to the Northwell Health Foundation from an entity that is i) the sponsor of research at the Feinstein, Northwell Health or a Northwell Health owned or controlled entity, or ii) the manufacturer of a product to be studied or tested in research at or under the auspices of the Feinstein, Northwell Health or a Northwell Health owned or controlled entity.

Disclosures

Relationships and potential transactions that warrant disclosure must be reported regularly by institutional officials, the Office of Northwell Ventures, Procurement, Foundation, Grants Management Office, Office of Technology Transfer Research Administration and others as applicable to the Office of Corporate Compliance, who will evaluate each case and determine whether further review is required. Potential institutional COIs shall be managed prior to finalization of any institutional transaction.

The Office of Corporate Compliance will request quarterly reports from Northwell Health offices with information related to investments, licensing, corporate donations related to research and research funding to identify any potential institutional conflicts that should be evaluated.

Review Process

When deemed necessary by the Office of Corporate Compliance or Research Compliance, certain disclosures will be escalated for further review to determine whether the interest disclosed represents an institutional COI.

Review of Non-Research-Related Disclosures

The SVP, Chief Corporate Compliance Officer will review potential institutional conflicts related to business transactions with applicable stakeholders. Institutional conflicts involving key employees, trustees, material amounts or unique cases will be presented to the Northwell Health Audit and Compliance Committee of the Board of Trustees for discussion and concurrence of any proposed management plan.

Review of Research-Related Disclosures

The Office of Research Compliance will review potential institutional conflicts related to research through the Institutional Conflicts of Interest Committee (ICIC).

Committee Review

The purpose of the institutional COI committee review is:

1. To review the establishment of an entity by any Northwell Health owned or controlled entity that will be engaged in Business or Research Activity;
2. To evaluate any implications for the Northwell Health's 501(c)(3) status;
3. To evaluate the roles and responsibilities of management for the entities;
4. To evaluate the overall appropriateness of the relationship and risk of undue influence; and
5. To evaluate the potential impact of the relationship on research integrity, objectivity and subject safety.

The Executive VP for Research will appoint a standing committee to review documentation and to make determinations with respect to the resolution of existing or potential Institutional financial conflicts of interest related to research. Details regarding committee membership is outlined in the respective charter.

Legal will review terms and conditions of the agreement/contract between the Northwell Health and the external entity in order to ensure that all agreements/contracts are executed at arm's length.

The scientific merit of research proposals may be evaluated by the Chief Scientific Officer or designee as necessary.

Committee meetings will occur at least annually and on an as needed basis thereafter. No meetings will be held in quarters where there are no disclosures warranting committee review. Subject matter experts or members of other departments (e.g., North Shore Ventures, Technology Transfer, etc.) may be called to provide input on an ad hoc basis and will not retain voting rights.

The Committee will assess whether there is a potential for an institutional COI concurrent to Northwell Health negotiations pertaining to a transaction that has, or appears to have a significant impact on research or business activities, or raises unusual questions of public interest or public policy. The Committee shall make a determination through a majority vote whether an institutional COI exists, that is, if the Committee believes that the interest disclosed could affect or appear to affect the design, conduct or reporting of any research or educational activities which are the subject of the Research Activities, or may have the opportunity or appear to have the opportunity to influence research, business, or clinical decisions of Northwell Health or the Feinstein.

Management Plans for Institutional COI

The Committee will consider appropriate management of the conflict and document any actions that have been or shall be taken to manage the institutional COI in a management plan.

Considerations for Research

For research related activities, the committee will differentiate between research that is clinical and non-clinical. The potential risks are greater with human subject research and any proposed management plans shall address such risks.

Non-Human Subjects Research:

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

Human Subjects Research:

When a potential Institutional COI that involves a human subject research project is identified, Research Compliance will notify the reviewing IRB and the Grants Management Office (if the institutional COI involves a sponsored project). When a potential institutional COI is identified in a project involving human subjects, the Committee shall apply a default position that either the financial interest should be eliminated or the human subject research should not be conducted at the institution.

The presumption may be rebutted if the circumstances and justification are deemed compelling by the Committee, and provided that the Committee approves an effective institutional COI management plan. Whether the presumption is successfully rebutted will depend in each case upon an analysis of:

- the nature of the science,
- the nature of the overlapping interests,
- how closely the interest is related to the research,
- the degree to which the interest may be affected by the research,
- the justification for conducting the research at the institution versus conducting it externally,
- the degree of risk that the research poses to human subjects and the integrity of the research, and
- the degree to which the institutional COI can be effectively managed.

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

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

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

Examples of management plan elements include, but are not limited to:

1. Disclosure of the institutional COI to human research participants in the informed consent process;
2. Where the institutional COI involves an institutional official, formal recusal of the conflicted official from the chain of authority over the project and possibly also from

authority over salary, promotion, and space allocation decisions affecting the investigator, as well as communication of the recusal arrangements to the official's superior and colleagues.

3. Where the institutional COI involves an institutional official, designation of a "safe haven" (e.g., a non-conflicted senior individual) with whom the investigator can address institutional COI-related concerns;
4. Use of an external Institutional Review Board (since most institutional IRBs are composed of faculty and staff from the institution);
5. For multi-center trials, avoid serving as the primary or coordinating site.
6. External monitoring of the study, to protect the design, conduct and reporting of the research against potential bias, particularly endpoint assessments and for single site studies;
7. Use of an external Data Safety Monitoring Board or similar review board to evaluate the design, analytical protocols, and primary and secondary endpoint assessments, and to provide ongoing evaluation of the study for safety, performance issues and the reporting of results;
8. Use of an external, third party entity to provide an independent analysis and validation of study results;
9. Disclosure of the institutional COI in public presentations and publications;
10. Disclosure of the institutional COI to other centers in a multi-center trial;
11. Separation of financial investments or management decisions by an independent entity;
12. Reduction or elimination of the institutional financial interest. (e.g., divestiture of an equity interest, etc.)

Reporting

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

Research Compliance will communicate the final research committee determination and approved management plan to the relevant institutional offices (e.g., IRB, IACUC, etc.).

Records

Northwell Health 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 or business activities to which they relate, or the resolution of any government action involving those records.

Confidentiality

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

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

Auditing and Monitoring

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

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

REFERENCES to REGULATIONS and/or OTHER RELATED POLICIES

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

CLINICAL REFERENCES/PROFESSIONAL SOCIETY GUIDELINES

N/A

ATTACHMENTS

N/A

FORMS

N/A

APPROVAL:	
Northwell Health Policy Committee	5/24/18
System PICG/Clinical Operations Committee	6/21/18

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