



POLICY/GUIDELINE TITLE: Review of External Consulting Relationships with Industry for Researchers	ADMINISTRATIVE POLICY AND PROCEDURE MANUAL
POLICY #: GR078	CATEGORY: Research
System Approval Date: 6/21/18	Effective Date: 7/2010
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Prepared by: Office of Intellectual Assets Office of Legal Affairs	Notations: N/A

GENERAL STATEMENT of PURPOSE

The purpose of this policy is to describe the internal review process applicable to Feinstein Researchers (defined below) who seek approval to provide consulting services to Industry (defined below). This policy applies when Feinstein Researchers seek to perform such services in their personal capacity and not on behalf of Northwell Health or the Feinstein Institute for Medical Research.

POLICY

External consulting relationships between Feinstein Researchers and Industry require pre-approval by the Researcher’s Department Chair, Center Head, Nurse Executive or Executive/Senior Vice President, as applicable as to scope of services and to ensure these agreements contain the appropriate appendices to mitigate any potential issues.

Feinstein Researchers who are contemplating an external consulting relationship must review Northwell Health policies 800.04 *Gifts and Interactions with Industry*, 100.024 *Policy on Intellectual Property*, 100.027 *Policy on Technology Licensing and Distribution of Royalty Income*, GR021 *Research Data Ownership*, and GR065 *Review and Management of External Interests (COIs) in Research (Individual)* before proceeding. In addition, Feinstein Researchers who are contemplating an external consulting relationship are advised to seek legal advice from their own attorney before signing any agreement.

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

External consulting relationships are personal arrangements between a Feinstein Researcher and an external company or other third party (including Industry).

Feinstein Researchers or Researchers are individuals conducting research at or on behalf of Northwell Health, individuals employed by The Feinstein Institute for Medical Research (Feinstein), or individuals holding Feinstein faculty appointments who are conducting research at or on behalf of Feinstein.

Industry means pharmaceutical, biotechnology, medical device and other healthcare-related entities and their employees, representatives and other agents.

PROCEDURE/GUIDELINES

External consulting relationships between Feinstein Researchers and Industry must be documented in a signed writing and disclosed to and pre-approved as follows:

If the Feinstein Researcher is a chairperson, the Chief Medical Officer must review and approve the consulting relationship.

For Feinstein Researchers in the research laboratory or support setting, the Center Head and Senior Vice President, Research or his/her designee must review and approve the consulting relationship.

For Feinstein Researchers in the clinical setting, the Researcher's Department Chair or Nurse Executive must review and approve the consulting relationship.

For Feinstein Researchers with Feinstein faculty appointments, the Executive Vice President, Research or his/her designee must review and approve the consulting relationship.

The role of the Center Head, Department Chair, and Nurse Executive, as applicable, is to determine whether the proposed consulting relationship is consistent with the Researcher's duties and commitment to Northwell Health/Feinstein (*i.e.*, no conflict of commitment).

The role of the Chief Medical Officer and Executive/Senior Vice President, Research or his/her designee, as applicable, is to make sure that the Researcher's obligations to Feinstein are not compromised by the proposed consulting relationship.

External consulting agreements are personal agreements between the Researcher and the external company; Northwell Health and the Feinstein are not a party to the agreement. Ultimately, the Feinstein Researcher is personally responsible for ensuring that there is no conflict between his/her obligations to Northwell Health or Feinstein and his/her obligations to the external company. Further, the Feinstein Researcher is personally responsible (and legally liable) for

compliance with the terms of the external consulting agreement. EACH FEINSTEIN RESEARCHER IS THEREFORE STRONGLY ENCOURAGED TO OBTAIN LEGAL ADVICE FROM HIS/HER PRIVATE ATTORNEY PRIOR TO SIGNING AN EXTERNAL CONSULTING AGREEMENT. (See Appendix D for some example questions and issues for discussion.)

Feinstein Researchers who are considering a specific external consulting relationship must take the following steps:

1. Discuss the proposed external consulting relationship with his/her Department Chair, Center Head, Nurse Executive, Executive/Senior Vice President, or Chief Medical Officer, as applicable, to obtain appropriate approval, based on the Researcher's cumulative conflict of commitment/time for all of the Researcher's consulting relationships (that is, integrating all of the Researcher's consulting services such as participation on external advisory committees, study sections, editorial boards and the like).
2. Review relevant aforementioned Northwell Health policies regarding gifts and interactions with Industry, intellectual property, data ownership, and conflicts of interest in research.
3. Ensure that consulting duties will not adversely affect the amount of time or effort that must be devoted to academic duties (*e.g.*, research, teaching, writing) and that external consulting services are performed without reliance on Northwell Health resources (*e.g.*, laboratory facilities, equipment, students, staff or other departmental personnel); provided, however, that the mere *de minimis* use of Northwell Health resources such as telephone, personal computer, copiers and the like shall not constitute such prohibited reliance. Generally, a relationship that does rely on the use of Feinstein/Northwell resources must be undertaken through the Grants Management Office as a sponsored research project.
4. If the consulting relationship creates or appears to create, a conflict of interest it must be disclosed to the Office of Research Compliance and may require review by the Conflict of Interest in Research Committee (COIC). Examples of potential conflicts include, but are not limited to:
 - Feinstein Researcher receives significant research funding from the external company;
 - Feinstein Researcher conducts clinical studies for the external company;
 - Feinstein Researcher or his/her relatives have significant financial interests or an equity stake or ownership in the external company.

Role-based Conflicts: A Feinstein Researcher seeking to enter into an external consulting relationship is also evaluated if he/she (1) serves as an officer, director or in any other fiduciary role for the external company, whether or not remuneration is received for such service; and/or (2) has a research study leadership role (*e.g.* Global or National Principal Investigator (PI) or Executive /Steering Committee member) or sits on a Data Safety Monitoring Committee and receives confidential information regarding

the research trial. Such individuals are generally restricted from serving as the local PI at Northwell Health or as an enrolling investigator. See the Global/National PI and Study Leadership COI Guidance for more information.

5. Ensure that any remuneration under the external consulting relationship does not exceed fair market value compensation fees for specific, legitimate services provided by the Feinstein Researcher for work actually performed. Payment must be commensurate with time and effort and the terms of the arrangements, services provided, and compensation must be set forth in advance and in writing. Any reimbursement for travel, lodging, and meal expenses must be reasonable and directly related to the engagement and documented in writing.

Remaining Steps for Feinstein Researchers are as follows:

6. Communicate to the external company Feinstein's Required Consulting Agreement Provisions (Appendix B) and provide the external company contact with a copy of the Consulting Agreement Addendum (Appendix C) for review. The external company is strongly encouraged to sign this Addendum, as written, to expedite review and approval.
7. Obtain the proposed consulting contract from the company and review it (along with the Consulting Agreement Addendum).
8. Complete (including signatures) the Consulting Relationship Approval Form (Appendix A) and provide a copy of the proposed consulting agreement to the Executive Vice President, Research or his/her designee for review. An expedient review and approval will be facilitated if the Consulting Agreement Addendum has been signed by the external company, as written, and included with the Approval Form. To the extent the company proposes revisions to the Consulting Agreement Addendum, the Executive Vice President, Research or his/her designee will communicate approval or any requested revisions to the Feinstein Researcher, who will be responsible for interacting with the external company or his/her own attorney to negotiate a final draft that can be approved.

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 may lead to disciplinary action, up to and including termination of employment.

REFERENCES to REGULATIONS and/or OTHER RELATED POLICIES

- 800.04 Gifts and Interactions with Industry
- 100.024 Policy on Intellectual Property
- 100.027 Policy on Technology Licensing and Distribution of Royalty Income
- GR021 Research Data Ownership
- GR065 Review and Management of External Interests (COIs) in Research (Individual)
- Global/National PI and Study Leadership COI Guidance

CLINICAL REFERENCES/PROFESSIONAL SOCIETY GUIDELINES

- N/A

ATTACHMENTS

- APPENDIX A - Consulting Relationship Approval Form
- APPENDIX B - Required Consulting Contract Provisions
- APPENDIX C - Consulting Agreement Addendum
- APPENDIX D - Issues to Discuss With Your Attorney

FORMS

- N/A

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

Standardized Versioning History:

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