

## Northwell Health

<b>POLICY TITLE:</b> Review of External Consulting Agreements with Industry for Researchers	<b>ADMINISTRATIVE POLICY AND PROCEDURE MANUAL</b>
<b>POLICY #:</b> GR078	<b>CATEGORY:</b> Research
<b>System Approval Date:</b> 4/21/16	<b>Effective Date:</b> 7/10
<b>Site Implementation Date:</b> 6/3/16	<b>Last Revised/Revised:</b> 9/15
<b>Prepared by:</b> Research Administration	<b>Superseded Policy(s)/#:</b> N/A

### GENERAL STATEMENT of PURPOSE

The purpose of this policy is to describe the process for reviewing external consulting agreements from Industry entered into by individuals conducting research at or on behalf of Northwell Health, individuals employed by the Feinstein Institute for Medical Research (“the Feinstein”) or holding Feinstein faculty appointments conducting research at or on behalf of the Feinstein (“Feinstein Researchers”) as required by Northwell Health policy 800.04 -- Gifts and Interactions with Industry.

### POLICY

Consulting relationships between Researchers and industry or other third parties require pre-approval from their appropriate Department Chair/Center Head. Feinstein employees and Feinstein Researcher require pre-approval from the Senior Vice President for Research or designee, through the Office of Technology Transfer to ensure these agreements are structured in appropriately to mitigate any potential issues.

Researchers who are contemplating a consulting relationship must review Northwell Health policies 800.04 Gifts and Interactions with Industry, 100.024 Policy on Intellectual Property, 100.027 Policy on Technological 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, researchers who are contemplating a consulting relationship are advised to seek legal advice from their own attorney before signing any agreement.

### 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**

**External consulting agreements** are personal agreements between the researcher and the company.

**Feinstein Researchers** are individuals employed by The Feinstein Institute for Medical Research or holding Feinstein faculty appointments conducting research at or on behalf of The Feinstein Institute for Medical Research.

## **PROCEDURE/GUIDELINES**

Northwell Health policy 800.04 Gifts and Interactions With Industry requires that all consulting relationships must be disclosed to, and approved by, the consultant's Administrative Director, Chairperson or similar position. A chairperson requires review and approval from the Chief Medical Officer. For Feinstein researchers in the laboratory this is the Center Head and Senior Vice President for Research or designee; for researchers in the clinical setting this is a Department Chair or Nurse Executive; and for researchers with Feinstein faculty appointments this is the Senior Vice President for Research or designee. The role of the Center Head/Department Chair/Nurse Executive is to determine whether the proposed consulting relationship is consistent with the researcher's duties. The role of the Senior Vice President for Research or designee is to make sure that the researcher's obligations to the Feinstein are not compromised by the proposed consulting relationship.

External consulting agreements are personal agreements between the researcher and the company — Northwell Health and the Feinstein are not a party to the agreement. Ultimately, the researcher is personally responsible for ensuring that there is no conflict between his/her obligations to Northwell Health or the Feinstein and his/her obligations to the company. Further, the researcher is personally responsible (and legally liable) for compliance with the terms of the consulting agreement. **EACH RESEARCHER IS THEREFORE STRONGLY ENCOURAGED TO OBTAIN LEGAL ADVICE FROM HIS/HER PRIVATE ATTORNEY PRIOR TO SIGNING A CONSULTING AGREEMENT.**

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

1. Discuss the proposed consulting relationship with his/her Department Chair/Center Head/Nurse Executive/Chief Medical Officer to obtain appropriate approvals.
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 is devoted to academic duties (e.g., research, teaching, writing, etc) and that consulting services are performed without reliance on Northwell Health resources (e.g., facilities, equipment, students, staff or other departmental personnel).
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:
  - consultant receives significant research funding from company
  - consultant conducts clinical studies for company
  - consultant or his/her relatives have significant equity stake or ownership in company.

**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.

5. The consulting engagement must only include fair market value compensation fees for specific, legitimate services provided by him or her and 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.  
Remaining Steps for Feinstein Employees and Feinstein Researchers (however, other researchers can use templates and revise accordingly with their own legal counsel).
6. Communicate to the company Feinstein's Required Consulting Contract Provisions and provide company contact with a copy of the Consulting Agreement Addendum (Appendix C) for company's review. The 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 Addendum).
8. Complete (including signatures) the Consulting Agreement Approval Form (Appendix A) and provide a copy of the proposed agreement to the Senior Vice President for Research or designee for review. An expedient review and approval will be facilitated if the Addendum has been signed by the company, as written, and included with the submission form.

The Senior Vice President for Research or designee will communicate approval or any requested revisions to the researcher, who will be responsible for interacting with the 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.northshore-lij.ethicspoint.com](http://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**

- 800.04 Gifts and Interactions with Industry
- 100.024 Policy on Intellectual Property
- 100.027 Policy on Technological 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**

N/A

**FORMS**

N/A

**APPENDICES**

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

<b><u>APPROVAL:</u></b>	
System Administrative P&P Committee	7/13/2010; 7/30/15; 3/31/16
System PICG /Clinical Operations Committee	7/29/2010; 9/17/15; 4/21/16

Versioning History:

7/29/10

9/17/15