

Review of External Consulting Agreements with Industry

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 The Feinstein Institute for Medical Research (“researchers”) as required by Section II of Health System policy 800.04 -- Gifts and Interactions with Industry.

POLICY

Consulting relationships between researchers and industry or other third parties require pre-approval from both the appropriate Department Chair/Center Head and 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 the Health System’s policies on Gifts and Interactions with Industry, Intellectual Property, Data Ownership, and Conflicts of Interest in Research before proceeding. In addition, researchers who are contemplating a consulting relationship should seek legal advice from their own attorney before signing any agreement.

SCOPE

This policy applies to all members of the North Shore – LIJ Health System work force but not limited to employees, business associates, medical staff, volunteers, students, physician office staff, and other persons performing work for or at North Shore – LIJ Health System and who are conducting research at or on behalf of The Feinstein Institute for Medical Research (“researchers”).

PROCEDURE/GUIDELINES

North Shore-LIJ policy 800.04 requires that all consulting relationships must be disclosed to, and approved by, the consultant's Administrative Director, Chairperson or similar position. For 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 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 is to make sure that the researcher’s obligations to the Feinstein are not compromised by the proposed consulting relationship.

Consulting agreements are personal agreements between the researcher and the company — Feinstein is not a party to the agreement. Ultimately, the researcher is personally responsible for ensuring that there is no conflict between his/her obligations to 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.
2. Review relevant policies, including Gifts and Interactions with Industry, Intellectual Property, Data Ownership, and Conflicts of Interest in Research. For example, the consultant must be able to perform consulting duties without adversely affecting the amount of time or effort that he/she devotes to his/her academic duties (e.g., research, teaching, writing, etc). Therefore, the consulting services must be performed without reliance on Feinstein resources, including facilities, equipment, students, staff or other departmental personnel.
3. If the consulting relationship creates or appears to create, a conflict of interest it must be disclosed to the Conflict of Interest in Research Committee (COIC). For example:
 - 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
4. 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.
5. Communicate to the company Feinstein's Required Consulting Contract Provisions and provide company contact with a copy of the Addendum to Consulting Agreements for company's review. See Appendixes A and B. The company is strongly encouraged to sign this Addendum, as written, to expedite review and approval.
6. Obtain the proposed consulting contract from the company and review it, (along with the Addendum).
7. Complete the Consulting Agreement Submission Form (including signatures), 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.

REFERENCES to REGULATIONS and/or OTHER RELATED POLICIES

- GR017 Intellectual Property
- GR021 Research Data Ownership
- GR065 Conflict of Interest in Research (Individuals)
- 800.04 Gifts and Interactions with Industry

- APPENDIX A - REQUIRED CONSULTING CONTRACT PROVISIONS**
- APPENDIX B - Consulting Agreement Addendum
Consulting Agreement Application**
- APPENDIX C - Issues to Discuss With Your Attorney**

SITE APPROVAL: To Include Committee Name / Approval Date	
System P&P Committee	7/13/2010
System PICG Committee	7/29/2010

APPENDIX A - REQUIRED CONSULTING CONTRACT PROVISIONS

The following provisions must be included in all consulting agreements. This requirement can be met by attaching the Addendum to Consulting Agreements document, which is to be signed by the company and the consultant.

Primacy of Your Obligations to Feinstein

The consulting agreement must contain a provision which states that 1) the company acknowledges that the terms and conditions of the consulting agreement are subordinate to obligations which you have to Feinstein as an Feinstein faculty member and employee, and 2) in the event that there is any conflict or inconsistency between terms of the consulting agreement and your obligations to Feinstein, the obligations to Feinstein will govern.

Intellectual Property

As an employee of Feinstein, all inventions made by you using Feinstein resources are the property of Feinstein. The consulting agreement must acknowledge the fact that under Feinstein's Intellectual Property Policy, you are required to assign to Feinstein any intellectual property conceived or made by you as a result of research that has been or is supported entirely or partly by Feinstein resources.

Non-Use of Feinstein Name

The consulting agreement must state that company may not use the name of The Feinstein Institute for Medical Research or the North Shore-LIJ Health System (including any variations or adaptations thereof)

Feinstein is Not a Party and Has No Liability

It must be clear that Feinstein is not a party to the consulting agreement and has no liability under the agreement. The consulting agreement is between the faculty member and the company.

APPENDIX B**CONSULTING AGREEMENT SUBMISSION FORM**

This form is to be completed and signed by Feinstein faculty members for submission of consulting agreements for review by the Senior Vice President, Research. Signature by the department chair or center head signifies that consultant has obtained departmental approval to enter into a consulting relationship with the company.

Upon completion of the review, the Senior Vice President, Research will return an approval notice or set of comments to the faculty member as appropriate. Revisions to conform to Feinstein's policies on intellectual property and academic obligations may be required.

This form will be signed by the Senior Vice President, Research and a copy will be returned to the faculty member to indicate acceptance of the final version of the consulting agreement. A photocopy or scan of the fully executed agreement should be provided to the Senior Vice President, Research for our records.

Faculty Name: _____
Faculty Department: _____
Department Chairperson/Center Head: _____
Company/Organization Consulting for: _____

By signing and submitting this form the undersigned faculty member confirms that he/she (i) has read and understands the GUIDELINES FOR CONSULTING RELATIONSHIPS BETWEEN FEINSTEIN FACULTY AND THIRD PARTIES, (ii) understands that he/she will be personally responsible (and legally liable) for compliance with the terms of the consulting agreement and (iii) understands that he/she is STRONGLY ENCOURAGED TO OBTAIN LEGAL ADVICE FROM AN ATTORNEY PRIOR TO SIGNING A CONSULTING AGREEMENT.

Signatures:

_____ Faculty Consultant	_____ Date
_____ Approved by: Dept. Chair	_____ Date
_____ Approved by: Senior Vice President, Research	_____ Date

APPENDIX C: ISSUES TO DISCUSS WITH YOUR ATTORNEY

Definition of the Scope or Field of Work

Is the scope of work defined as narrowly and specifically as possible to avoid the potential for conflicts with your academic research and your obligations to Feinstein?

Confidentiality Provisions

Are you obligated to keep secret and not use the company's confidential information? Are the restrictions and obligations that the company seeks to impose on you reasonable? What happens if you accidentally disclose some of the company's confidential information? Could you be liable for damages?

Liability & Indemnification

Are you required to indemnify the company for any damages that result from your performance of your consulting services? Are you liable to the company if your consulting services are performed in a negligent manner? Will the company indemnify you if you are sued by a third party as a result the performance of your consulting services? Are you being asked to make any representations or warranties? Are these representations and warranties reasonable and appropriate?

Non-Compete Provisions

Are you precluded from entering into consulting or other agreements with other companies? Is this preclusion narrow or broad?

Governing Law and Jurisdiction

Are you being asked to travel to another state to defend yourself if a dispute arises between you and the company?

Remedies

Are you being asked to agree to an injunction in the event of your breach of the agreement? Is this fair and reasonable?

Termination Provisions

Can you terminate the agreement whenever you desire? Under what circumstances can the company terminate the agreement?

"Best efforts" vs. "reasonable efforts" wording

Are you required to use "best efforts" to perform your consulting obligations? What does this phrase mean?

Use of Your Name

Does the company have the right to use your name in any way? Does the company need to get your permission first?