

	Institutional Policy	
	Policy Name	Conflict of Interest and Commitment Policy
	Effective Date	10/23/2017
	Approved Date	10/23/2017
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	Policy Owner	Alicia Christensen
Approved by: Michael Salem, CEO		

POLICY STATEMENT

The success of National Jewish Health (NJH) depends on its talented, skillful, creative faculty and staff whose contributions to teaching, research, clinical care and other professional activities are recognized in their diverse clinical, research, and professional specialties. Because of their expertise, faculty and staff have opportunities to participate in activities with commercial entities, professional and scientific organizations and journals, other academic organizations and government agencies.

NJH accepts the principle that it is privileged to serve as a public trust for the conduct of clinical care, research, and for the advancement, preservation, and dissemination of knowledge. To that end, NJH has developed policies designed to protect human subjects, preserve and enhance institutional integrity and reputation, and recognize and support the creativity and vision of its researchers, clinicians, and staff.

The relationships between NJH (Institution), the individual employees of NJH, private industry, federal and state governments, and the non-profit sector have grown increasingly complex. As a result, there are opportunities for professional interactions and development that may benefit the Institution and its employees, but which may also present the potential for or the appearance of conflicting interests and responsibilities for NJH employees.

SCOPE

This policy applies Enterprise-wide to all persons affiliated with NJH, including without limitation board members, faculty, researchers, clinicians, fellows, affiliates, and all other staff employed or working at National Jewish Health. Additionally, Scientist engaged in research under the auspices of NJH.

PURPOSE

The purpose of this Policy is to establish the standards for determining the existence of conflicts of interest, the requirements for disclosing conflicts, and the process for reducing, managing or eliminating conflicts. This Policy is also intended to make NJH compliant with the requirements of 42 CFR 50 Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service (PHS) Funding is Sought.

DEFINITIONS

Conflict of Interest: The term “Conflict of Interest” (COI) refers to situations in which financial, professional, or other personal considerations may compromise, or may have the appearance of compromising an individual’s professional judgment in exercising NJH duties and responsibilities. A COI arises when a Covered Individual or NJH has a direct or indirect interest in an organization doing business with NJH. Many types and degrees of interest may create a conflict, for example: Financial Interest in a vendor—including employment with a vendor—and/or the prospect of professional advancement or financial or business reward in any form.

Consulting: The situation wherein a Covered Individual spends any time or effort in assisting, advising, and/or in any way facilitating the mission or enterprise of any kind of company, whether or not there is compensation or other considerations and whether or not the Consulting is done on the Covered Individual’s own time.

Controlled Entity: A for-profit entity, publicly traded or not, in which the Covered Individual and/or an Immediate Family member has a material ownership position. Material ownership is considered to be an estimated 5-percent-or-greater ownership and/or management influence through Board representation, advisory role, and/or similar role. A Controlled Entity is considered to be a Significant Financial Interest.

Covered Individual: Includes, but is not limited to, NJH faculty (employed or otherwise), Board of Directors, research staff, management staff, all other staff and affiliates who spend a majority of their time at NJH. Individuals who are employed by other institutions (such as the University of Colorado) (“third parties”) but work at NJH must complete a COI declaration for the third party and provide a copy of COI declaration for such third party to the NJH CCO.

Corporate Compliance Committee (CCC) – A group of NJH senior executives, directors, faculty, other staff, and/or lay individuals selected by the CEO and/or CCO to review actual or potential COI, that may be either individual or institutional, and make recommendations to resolve or manage a COI.

Corporate Compliance Officer (CCO): An individual appointed by the NJH CEO to oversee and manage all issues of individual or corporate compliance, including COIs. The NJH CEO has appointed the VP of Legal and Regulatory Affairs, Chief Compliance Officer (CCO) of NJH as the CCO.

Disclosure Statement: A Covered Individual’s disclosure of Financial Interest/Significant

Financial Interest to NJH as required by policy.

Equity or Equity Interest: Includes, but is not limited to, stock, stock options, warrants, and ownership rights in any entity whether or not the entity is publicly traded. An Equity Interest in a publicly traded corporation will not be considered a Financial Interest if the Equity Interest exists through ownership of shares in a publicly traded mutual fund. A Financial Interest of the Covered Individual's Immediate Family is considered to be a Financial Interest of the Covered Individual.

External Activity Review Form – The form shown in Exhibit C of this policy used by faculty and staff when required to request review and approval of external agreement and presentations.

Financial Interest: Anything of financial or monetary value that is associated either directly or indirectly with an activity that is directly related to a Covered Individual's responsibilities to NJH.

Financial Conflict of Interest (FCOI): A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of research.

Gifts: Refers to anything that is transferred from one individual or entity to another without the expectation of receiving something in return. Gifts do not include charitable donations as referenced in Section 12 of this policy. In the context of this policy Gifts include both Gifts from patients and Gifts from third parties' representatives. Examples of Gifts would include, but are not limited to meals/food, free CME, free registration to events, sporting events tickets, pens, coffee mugs, instruments, and supplies. Generally, modest meals or financial support sponsored by third parties provided for on campus activities in association with in-service training for non-physician staff is acceptable.

Immediate Family: Includes the Covered Individual's spouse/domestic partner and dependent children.

Industry: Refers to any vendor or potential vendor, or contractor who sells, or may sell products or services to the public and/or to NJH. This refers to, but is not necessarily limited to, pharmaceutical manufacturers, medical device manufacturers, and medical and laboratory suppliers, contractors or consultants.

Institutional Responsibilities: A Covered Individual's professional responsibilities on behalf of NJH, including but not limited to research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as institutional review boards or data safety monitoring boards.

Investigator: Any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, which may include, for example, collaborators or consultants.

Management Plan: A plan set forth by the CCO, the CCC or other review boards containing conditions that the Covered Individual must follow to ensure that the COI/FCOI

does not jeopardize the integrity of NJH.

Presentation Review Committee: A committee of NJH faculty and administration charged with review and approval of all externally sponsored or compensated presentations by faculty and staff to insure the presentations conform to NJH COI policy guidelines.

Scientist: A person who is, or expects to become, an Investigator with respect to research under the auspices of NJH.

Significant Financial Interest (SFI): A financial interest that could directly and significantly affect the design, conduct, or reporting of all research. The definition of SFI is divided into (1) interests in entities and intellectual property interest and (2) sponsored travel.

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

- With regard to any publicly traded entity, an SFI 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, an SFI 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
- Any intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators must also disclose the occurrence of any 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.

The term SFI does not include the following types of financial interests:

- Salary, royalties, or other remuneration paid by NJH to the Investigator if the Investigator is currently employed or otherwise appointed by NJH, including intellectual property rights assigned to NJH and agreements to share in royalties related to such rights.

- 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.
- 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.
- Travel reimbursed or sponsored by a Federal, state or local government agency, an Institution of higher education 20 USC 2002(a), academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

GUIDELINES

1. Financial Interest

When a Covered Individual has a Financial Interest in a business, such as an owner, board member, executive or employee, they must be aware that a COI may occur if the business has a relationship with or is a competitor of NJH. If the organization does business, is considering doing business, or is a competitor with NJH, the individual is expected to disclose that relationship.

2. Pharmaceutical Samples

- A. NJH faculty, students, and trainees may accept free drug samples from industry for distribution to patients, only when the free samples are provided directly to the NJH pharmacy. All distribution of free samples to patients must be administered by the NJH pharmacy.
- B. Free drug samples may never be sold.
- C. Free drug samples may not be used by clinicians for themselves, clinical faculty, family members, or NJH employees unless they are registered patients of NJH.

3. Site Access by Pharmaceutical Representatives

Vendor representatives from pharmaceutical, biotechnology or other industries may visit

NJH faculty and staff to discuss and demonstrate their products. While generally acceptable as straightforward sales visits, an appointment is highly encouraged (See Vendor Visit Policy – Procurement). Visits with faculty and staff in clinical areas are generally discouraged and vendors are not allowed in clinical areas unless escorted by NJH staff. Vendors may not access any patient-specific information (See HIPAA policy).

4. Participation in Industry-Sponsored Programs: Presentations Sponsored by Industry (Speakers Bureaus) and Industry Support of Educational Programs

Educational Program Support

Vendors and other industry representatives may provide unrestricted funds to departments or divisions at NJH for education programs. The funds will be managed according to the following NJH standards:

- A. All support for educational programs must be free of actual or perceived COI (individuals and institutional).
- B. All such funds must be given to NJH as an unrestricted grant or Gift. The funds cannot be given to an individual faculty member, student or staff. This requirement applies to all funds for meals and refreshments, speaker's honoraria, and any other expense related to an educational program and includes noon conferences, grand rounds, and lectures at all NJH sites. Funds that are provided by educational groups or other entities that act as "intermediaries" for associations, professional societies, or industry must also be provided as unrestricted grants.
- C. No gifts may be accepted in exchange for listening to a lecture or presentation by a representative of a commercial entity that produces health care or medical goods and services.
- D. The content of all educational programs will be determined by the NJH department planning the event or when appropriate the Continuing Medical Education (CME) department. Industry sponsors of educational programs may not determine the content or selection of speakers for educational programs.
- E. These requirements do not apply to meetings governed by the Accreditation Council for Continuing Medical Education (ACCME) Standards or meetings of professional societies or other professional organizations that may receive partial industry support.

Presentations and Speakers Bureaus

Presentations or speakers bureaus are defined as any compensation to an individual by any pharmaceutical company, medical device manufacturer, or manufacturer of other health or nutritional related products, or their subsidiaries, for presenting or speaking on that company's behalf whether on a one-time or recurring basis.

NJH faculty and staff are prohibited from making presentations that are sponsored by industry as defined in the above paragraph unless the presentation is prepared and presented within specified guidelines and with appropriate institutional approval.

Talks on scientific discovery, research, clinical presentation of disease, disease recognition and treatment guidelines are permitted. **Talks focused on specific products**

or devices, or talks that contain sales or marketing promotional information are prohibited. The CCO shall review and approve the format and content of all outside presentations where sponsorship or compensation is provided to the speaker by industry. This includes slide-based talks and non-slide based forums. Non-slide based presentations/talks include such forums as guided panel discussions and open question and answer forums.

This speakers' bureau policy does not preclude faculty members from receiving compensation from academic institutions when paid for by the institution, or presentation of Grand Rounds. If these events are industry sponsored the above guidelines apply.

Consulting and service on Scientific Advisory Boards, and compensation for those services, are not prohibited by this policy.

Individuals who speak in meetings and conferences supported in part or in whole by industry (e.g., by giving a lecture, organizing the meeting) must follow these guidelines:

- A. Financial support by industry is fully disclosed to the audience by the speaker and the meeting sponsor.
- B. The meeting or lecture content is determined by the speaker and not the industry sponsor and preapproved by the NJH Presentation Review Committee. Industry sponsors may work in collaboration with NJH in developing materials (slides) for non-marketing, non-promotional educational faculty presentations. Outside industry sponsors may help support the development of these non-promotional, non-branded presentation materials and their support may be acknowledged during the presentation. Industry sponsors shall not be permitted to provide product or device marketing, sales, or promotional materials before or after presentations. Procedures for obtaining review of contracts and speaking engagement are found in Exhibits B and C of this policy.
- C. The NJH CCO and/or the NJH Presentation Review Committee shall review and approve the format and content of all outside talks, including associated AV materials, which are compensated by industry.
- D. The lecturer is expected to provide a fair and balanced assessment of therapeutic options and promote objective scientific and educational activities and discourse.
- E. Product or sales promotional talks are prohibited.
- F. The NJH participant must not be required by an industry sponsor to accept advice or services concerning speaker, content, etc. as a condition of the sponsor's contribution of funds or services.
- G. Compensation for services shall be at fair market value. Fair market value is the generally accepted contract rate for speaking as shall be determined through NJH review of speaking engagement contracts.
- H. The use of the NJH name in non-NJH events is limited to the identification of the individual by his or her title and affiliation.

NJH faculty, trainees, or staff may not accept compensation, including the defraying of costs, for simply attending a CME program or other activity or conference (that is, if the individual is not speaking or otherwise actively participating or presenting at the event). Faculty, trainees, and staff should very carefully evaluate their own participation in

meetings and conferences that are fully or partially sponsored or run by industry because of the high potential for perceived or real conflict of interest. This paragraph does not apply to meetings of professional societies that may receive partial industry support and meetings governed by ACCME Standards.

5. Industry-Sponsored Scholarships and Other Educational Funds for Trainees

A. Industry support of students and trainees should be free of any actual or perceived conflict of interest, must be specifically for the purpose of education and must comply with all of the following provisions:

1. NJH Department, Division, or Program selects the student or trainee.
2. The funds are provided to NJH and not directly to the student or trainee.
3. The Department, Division or Program has determined that the funded conference or program has educational merit.
4. The recipient is not subject to any implicit or explicit expectation of providing something in return for the support, i.e., a “quid pro quo”.

B. This provision shall not apply to national or regional merit-based awards, which are considered on a case-by-case basis.

6. Gifts

NJH personnel shall not accept or use personal gifts or gratuities from representatives of industry regardless of the nature or dollar value of the gift whether on-campus or off-campus, or accept complimentary tickets to sporting or other events, or other hospitality from industry, except as noted in Section 7 below. Exceptions to this policy are events organized and sponsored by NJH and other non-profit organizations for the purposes of fundraising (e.g., Beaux Arts Ball), or professional society meetings. All charitable gifts to NJH must be approved by the NJH Finance department before being accepted.

Industry wishing to make charitable contributions to NJH may contact the NJH Development Department. Such contributions shall be subject to any applicable policies maintained by NJH.

7. Food

Meals or other types of food directly funded or supplied by industry may not be provided at NJH events, on or off campus, unless in connection with an ACCME-accredited program and in compliance with ACCME guidelines. Modestly priced meals/food in the context of legitimate business meetings or non-commercial scientific meetings are an exception to these guidelines as are modest food/meals provided by established vendors to non-physician staff in the course of in-service training or business operations.

8. Ghostwriting

Individuals are prohibited from publishing articles under their own names that are written in whole or material part by industry employees. See NJH policy on Guidelines for Authorship (Ghostwriting).

9. Purchasing

NJH faculty, trainees, and employees who are involved in the purchase of, or approval of, medications, supplies or equipment, or the negotiation of other purchasing decisions or contractual relationships with industry must not have any Financial Interest (e.g., equity ownership, compensated positions on advisory boards, a paid consultancy or other forms of compensated relationship) in the vendor that might benefit from the institutional decision. This provision is not intended to preclude an employee's indirect ownership, through mutual funds or other investment vehicles.

NJH Faculty, Trainees and Employees must disclose their actual and potential conflicts of interest related to any institutional deliberations and generally may participate in deliberations in which they have an actual or potential conflict of interest if they have unique knowledge of the products' merits and demerits and if the conflict is disclosed both to the CCO and to the manager in charge of the purchasing recommendation or decision making.

10. Outside Speakers Sponsored by Industry

Presentations by outside speakers sponsored by the pharmaceutical or device manufacturing industry are allowed at events sponsored by NJH (whether on NJH campus or off-campus) as long as:

- A. The speaker discloses his/her sponsorship by the industry sponsor;
- B. The talk is not a promotional talk designed to market any particular product or device; and
- C. The industry sponsor does not display any promotional, sales or marketing materials before or after the event.

11. No Product Endorsements

Because of real or perceived personal and/or institutional COI associated with product endorsements, faculty and staff are prohibited from publicly endorsing any consumer product, service, or device. This is not meant to prohibit any physician or other health care professionals from expressing his or her individual opinion and preferences to their patients, or endorsing methods of treatment (e.g. classes of drugs for certain conditions, or types of testing for diagnostic purposes) as long as no specific product is publicly endorsed. Approved speaking formats and contents that might include product references are not considered product endorsement under this policy.

12. Grants and Other Charitable Donations

Health care professionals may accept donations to the institution for a charitable purpose, such as supporting independent research or training for the advancement of medical science or education, indigent care, patient education public education, or the sponsorship of events where proceeds are intended for charitable purposes. To protect the charitable status and nature of the donation, such gifts must be made only to NJH, and not to the individual.

All donations should be appropriately documented and must be preapproved by the finance department prior to acceptance if there are any conditions or restrictions on the use or purpose of the donation.

It is not appropriate for healthcare professionals to accept donations for the purpose of inducing health care professionals to purchase, lease, recommend, use, or arrange for the purchase, lease or prescription of products. No grants, scholarships, subsidies, support, consulting contracts, educational or practice-related items should be provided or accepted by a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be accepted or provided in a manner or on conditions that would interfere with the independence of a healthcare provider.

13. Research Guidelines and Requirements

As a medical research institution, NJH has opportunities to collaborate with private industry in sponsorship of research. While collaboration most often results in the advancement of science, the application of new technologies and enhanced patient care, it can raise troublesome COIs/FCOIs for those engaged in research. In order to maintain its reputation and the highest ethical standards, it is critical that NJH apply its high ethical standards to the identification and resolution of these COIs/FCOIs as they arise. Examples of situations in which a COI/FCOI may arise that need to be reported and COIs/FCOIs that would generally require a management plan are outlined in Exhibit A to this policy.

Additional Requirements:

A. Training

All Investigators and Scientist must complete training on:

1. The PHS regulations applicable to FCOIs, as may be amended from time to time.
2. The portions of this Policy governing conflicts of interest in research.
3. Their obligations regarding disclosure to NJH of interests related to their Institutional Responsibilities.

Timing of Training

Investigators and Scientists must complete this training prior to engaging in research under the auspices of NJH, or as otherwise required by a relevant awarding agency, and at least every four years following the initial training. Additionally, Investigators and Scientists will be required to receive training immediately in any of the following circumstances:

1. NJH revises the portion of its policy governing conflicts of interest in research or procedures in any manner that affects the requirements applicable to Investigators and Scientists.
2. An Investigator and Scientist is new to NJH.
3. NJH finds that an Investigator and Scientist is not in compliance with the portion of NJH's policy governing conflicts of interest in research or an

imposed management plan.

B. Review Procedures

Please refer to Exhibit D.

C. Reporting

NJH will report FCOIs to research sponsors as required by law, regulation, contract or policy.

14. Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and Industry COIs.

NJH values and requires the expertise of faculty with research and scientific experience to review grant applications related to human research and animal research that are supported through both Federal and industry grants.

NJH faculty who receive industry financial support (e.g., receive compensation for speaking engagements, participate on scientific advisory boards, or on other industry boards, receive industry grants, or other services for compensation) have a real or perceived conflict of interest in fairly and impartially adjudicating industry sponsored research from an entity from whom they receive compensation, regardless of the amount.

Faculty members participating on any IRB or the IACUC must disclose their conflict of interest to the IRB or IACUC and recuse themselves from any deliberations and decisions related to any research protocol sponsored by a company with whom they receive compensation or have a Financial Interest.

15. Institutional Conflict of Interest

NJH itself can have interests in the outcome of research. This can arise because of actual or potential Financial Interests, intellectual property rights, or potential future grants or otherwise. Disclosure of Institutional COI will be required by any NJH employee as they become known. The CEO can delegate the investigation and management plan of the actual or potential COI to an appropriate individual. When there is such a conflict, the decision about how to handle it should be made by a group appointed by the CEO including members of the Board of Directors and individuals outside of NJH.

16. Conflicts of Commitment

Another type of conflict is Conflict of Commitment (COC). A COC occurs when an executive, faculty member, manager, or employee participates in activities, whether or not they enhance their knowledge and skills for their NJH position, that interfere with the individual's responsibilities in meeting their job responsibilities at NJH. It is the policy of NJH that all full-time staff and employees devote their primary

professional loyalty, time, and energy to their position at NJH. External activities should be conducted in a manner that will not discredit NJH, distract individuals from their primary responsibilities at NJH, or compromise intellectual property owned by NJH.

Faculty who do not accrue vacation must consider external activity time as time away from their NJH responsibilities and as time that does not count toward the expectation of work on behalf of NJH.

Activities of other staff and employees that could create a COC should be disclosed as described in this policy and discussed with the staff member's supervisor to ensure they won't cause a conflict of commitment.

This policy is not meant to prohibit employment outside NJH by any employee as long as no COI exists, the activity meets the above guidelines, and is conducted outside of NJH compensated time.

17. Mandatory Industry Contract Review

All contracts between NJH faculty and staff and outside industry must be reviewed and approved by the Legal and Regulatory Affairs Department, the Purchasing Department, the Chief Financial Officer (CFO) or the Chief Compliance Officer (CCO) before being signed. NJH CFO and CCO shall review the language and obligations of the agreements to ensure that the terms are consistent with NJH conflict of interest policies, conflict of commitment policies, and meet basic legal guidelines.

Procedures for obtaining contract review are found in Appendices B and C of this policy.

Contracts requiring review and approval include, but are not limited to, the following type of agreements:

- A. Non-disclosure agreements
- B. Material transfer agreement
- C. Research agreements
- D. Presentation and speaking agreements
- E. Consulting agreements
- F. Scientific Advisory Committee or Board of Director Agreements or Appointments for for-profit companies
- G. U.S. or Foreign Patent Applications

18. Disclosure and Implementation Policy

Disclosure Responsibility:

- A. It is the responsibility of all staff to consider the potential effect a conflict of any kind might have on their ability to carry out their job

responsibilities. All manner of relationships should be considered, including such clear-cut issues as financial interests in an NJH vendor, relatives employed by an NJH vendor, and other relationships that might suggest something other than an arm's length business relationship. Because the perception of COI/FCOI may vary from one individual to another, employees and staff should disclose all real and potential COIs/FCOIs which could be deemed by others to be significant.

- B. A COI Disclosure Statement will be required of all Covered Individuals, according to the following requirements:
 - i. Within 60 days of being hired.
 - ii. Annually or upon request by the CCO.
 - iii. Project-Specific Disclosure - in addition to the annual disclosure requirement, at the time of application for research funding and/or application to the IRB/IACUC for approval of research, all Investigators must confirm that their disclosures on file with NJH are correct and complete, or provide updated information when warranted, as well as provide any additional information required by NJH regarding financial interests related to the Investigator's Institutional Responsibilities (i.e. one cannot submit a grant, IRB protocol or IACUC protocol if a current disclosure is not on file).
 - iv. All Investigators must complete a revised Disclosure Statement within 30 days of discovering or acquiring a new Financial Interest.
 - v. All Investigators must complete a revised Disclosure Statement within 30 days of the occurrence of any trip for which there is reimbursement or sponsored travel.
- C. All Financial Interests must be disclosed so that they can be addressed.
- D. The Covered Individual will not be expected to make the determination of whether or not an actual COI exists. That decision will reside with the CCO. The CCO may request additional information pertinent to the potential conflict from the Covered Individual. The CCO may use the CCC in a consultative manner to help determine if a COI/FCOI exists and what, if any, plan of correction or management needs to be implemented.
- E. Communications regarding disclosures and determinations of COI shall be held in confidence unless this Policy itself calls for notice to certain people or to the public.
- F. Because this Policy cannot describe all potential COIs/FCOIs by specific provisions, all Covered Individuals should seek advice on transactions or activities that present a potential COI/FCOI or issues of confidentiality before committing to them. Questions concerning this Policy should be

addressed to the CCO, CFO, CEO or designee.

19. CCO – Management of Conflicts

The CCO shall review each COI Disclosure Statement in which actual or potential conflicts are identified, and if it is determined that a COI/FCOI exists, the CCO will decide how it might best be managed. The CCO will determine that one or more of the following courses of action will be required:

- A. Nothing needs to be done, since a COI/FCOI does not exist or is insignificant.
- B. With suitable constraints and cross-checks, the relationship or project should be permitted to proceed as planned.
- C. The conflicting Financial Interests involved are divested or the relationships that created the COI are severed.
- D. The reporting individual should be removed from any involvement with the activity.
- E. CCO may convene the CCC to review specific conflicts and assist in the development of a COI/FCOI management plan.
- F. A COI/FCOI on occasion may be so significant that the only recourse to resolve the conflict may be termination of the individual's employment with NJH.

20. Consequences of Failure to Comply

All Covered Individuals shall promptly complete their annual COI Disclosure Statement by the date specified by the CCO. Individuals who fail to complete their COI forms in a timely manner shall be subject to loss or reduction of their annual merit increases.

Faculty members who fail to complete their COI Disclosure Statement in a timely manner will be subject to loss or reduction of departmental bonus.

Failure to file a COI Disclosure Statement or omission or misrepresentation of the facts in COI disclosures will be considered a violation of NJH policy and may result in disciplinary action or fines at the discretion of the CCO or CEO including any of the actions described below.

Staff disciplinary actions may include:

- Reduction or loss of merit pay
- Reduction or loss of incentive compensation
- Termination of employment

Faculty disciplinary actions may include:

- Reduction or loss of bonus
- Fines depending on the degree and frequency of the policy violation:
 - The lesser of \$10,000 or 10% of base salary
 - The lesser of \$20,000 or 20% of base salary
- Loss of Faculty Privileges and/or Termination of Employment

21. Public Transparency

To ensure and maintain the public trust, all NJH faculty and staff are encouraged to divulge any actual or potential COI they have to patients, professional colleagues, and in public forums where the COI is relevant to the context of the public forum (– e.g., speaking engagements or publications).

NJH will disclose industry relationships on its public faculty profile web pages. These faculty disclosures shall be updated at least annually.

22. Colorado Department of Regulatory Agencies (DORA) Reporting Requirements and Michael Skolnik Medical Transparency Act of 2010

The Michael Skolnik Medical Transparency Act, administered by DORA, requires all individuals applying for the following licensure types (new or renewal licensure) to complete online profiles. Information about DORA requirements can be found on the DORA website or through the NJH Medical Staff office. Beginning July 1, 2011, the following licensure applications and renewal types are subject to this requirement:

Accountant
 Anesthesiology Assistant
 Audiology and Hearing Aid Provider
 Chiropractic
 Counselors, Addiction
 Counselors, Professional
 Dental
 Electrical
 Nursing, All Types
 Optometry
 Pharmacy
 Physician
 Physician Assistant
 Plumbers
 Podiatry
 Psychology
 Psychotherapy, Registered
 Social Work
 Speech Language – Pathologist
 Surgical Assistants and Technologists
 Therapy, Marriage and Family

Therapy, Massage
Therapy, Occupational
Therapy, Physical
Therapy, Respiratory
Veterinary

23. COI Policy Exceptions

Exceptions to this Conflict of Interest and Commitment Policy should be rare and can only be made by the CCO or CEO.

REFERENCES

42 C.F.R. § 50 and 45 C.F.R. § 94

REVIEWED BY:

Gregory Downey, Katherine Sanner, Ron Berge

EXHIBIT A
Examples of Potential Reportable COIs/FCOIs
COIs/FCOIs That May Require Management Plans

The following paragraphs provide examples of situations that may contain COIs/FCOIs. These situations generally should be disclosed on the NJH COI Disclosure Statement (found on the NJH Spyderweb site) and shall be reviewed by the CCO. The CCO will consider the conflict and prepare a plan to manage the conflict when required.

- a. Clinical research conducted at NJH in which the Covered Individual or an Immediate Family member has a SFI in the company sponsoring the research is not allowed except in very unusual circumstances. When allowed, special oversight will be required to ensure that the COI/FCOI does not interfere with the conduct and independence of the research or in any way compromise appropriate patient care.
- b. Clinical research conducted at NJH where NJH has a SFI related to the company or the subject of the research (such as a patent on a compound).
- c. Non-clinical research where the Covered Individual and/or an Immediate Family Member has a SFI in the sponsoring company.
- d. Clinical or non-clinical research in which the investigator has an ownership interest in, or receives compensation from, the company sponsoring the research whether it is for speaking, consulting, or serving on scientific advisory boards.
- e. Covered Individual is seeking or considering a research or management position in a for-profit organization that is currently involved with clinical, biomedical, or other closely related activities at NJH.
- f. Students, fellows, or other trainee positions are assigned to activities in which Covered Individuals and/or their Immediate Family have a Financial Interest. This COI must always be disclosed to NJH and to the trainee to ensure that the training experience is of the highest quality and that all involved individuals are aware of the potential COI. Trainees must be informed of project sponsorship, any significant Financial Interest of the Covered Individual, and any limitations that may be imposed on the dissemination of scientific findings.
- g. Financial or non-financial COI may arise when clinicians recruit their own patients for their research projects or encourage their patients' participation in the research of a colleague. While the potential for (subtle) coercion exists, we recognize that

in the overwhelming majority of cases clinicians are acting in good faith and that recruitment is based on appropriate and constructive criteria.

- h. Covered Individual accepts something of value from a for-profit company while in a position to influence the research of a colleague whose work is sponsored by that company.
- i. Covered Individual accepts something of value from a for-profit company and the Covered Individual advocates for a research proposal on behalf of the for-profit company, either to, or as a member of, the IRB.
- j. An institutional COI arises principally when an institution has equity, or the right to acquire it, in a company, and investigators employed by the institution conduct research that could affect the value of the equity interest. Institutional COI also arises when an institution holds or can acquire a patent on a compound, process, or therapy that it could license to companies, and investigators employed by the institution conduct research on that compound, process, or therapy.
- k. Covered Individuals are prohibited from offering or receiving compensation in any form for obtaining or referring human subjects to a NJH research project.
- l. The activities of the sponsor conflict with the mission of NJH (e.g., direct funding from tobacco companies).

In general, any of the above types of conflicts should be avoided at all times. If resolution of a COI/FCOI is impossible or impractical, precautions should be put in place to ensure that the Covered Individual's conflict does not unduly influence business decisions. It may be necessary to limit or prohibit the active participation of the Covered Individual in the decision. In this circumstance, appropriate notification, including a public declaration of the COI/FCOI, should be made. If adequate protections cannot be put in place or the protections in place prove to be unworkable, then either the COI/FCOI must be eliminated or the research and business relationship cannot go forward.

EXHIBIT B

Contract Review Procedures

The following procedure should be followed for review of faculty and staff agreements with outside parties listed in Section 17 of this policy.

1. All faculty wanting to conduct activities outside of National Jewish Health sponsored by industry must submit a fully completed External Activity Review (EAR) Form (See Exhibit C) that has been signed by the Division Head or Department Chair. The signature of the Division Head/Department Chair signifies that the activity is appropriate and the time commitment is within the guidelines that are allowed.
2. If there are visual aids used in a presentation sponsored by a for-profit company, or if the sponsor plays a role in determining the presentation format or Q&A, the EAR and any accompanying visual aids must be submitted electronically or in paper to the Legal and Regulatory Affairs Department for review.
3. Once all signatures are obtained, the EAR, any visual aids and the proposed contract must be submitted to the Legal and Regulatory Affairs Department. The faculty member is expected to have reviewed the contract terms prior to contract submission. Legal Affairs reviews agreements for National Jewish Health's interest and as a courtesy will point out issues that may not be favorable to the faculty/staff's own interests. Faculty should plan for a 2-week initial review of documents and 30 days total for approval. Please note: Faculty need to allow time to then submit the comments to the company and receive a revised agreement back if necessary. It may take additional time to resolve concerns over any contractual terms. Faculty must factor this time into their expectations and adjust their timeframes accordingly.
4. The Legal and Regulatory Affairs Department will review the contract for clauses that impact National Jewish Health such as Use of Institutional Resources, Ownership of Intellectual Property, and Indemnification Obligations of Institution. As part of this review, the Legal and Regulatory Affairs Department may determine that certain changes are required in order to protect National Jewish Health's interests.
5. Required Changes must be resolved before the Faculty Member can execute the agreement. If required changes cannot be made the Faculty Member cannot proceed with the activity. In no instance may Faculty Members sign a contract when National Jewish Health is named or impacted either directly or indirectly by the terms of such contract or agreement.
6. The Legal and Regulatory Affairs Department might also offer suggestions to the Faculty Member that he or she might want to consider changing based on best business practices. These are suggestions only. The Faculty Member may execute a contract without making these changes at his or her discretion.
7. The Legal and Regulatory Affairs Department will sign off on the EAR upon resolution of any required changes. Once the EAR has been completed, the Faculty Member may execute the contract.

A fully executed copy of the agreement must be returned to the Legal and Regulatory Affairs Department. The Legal and Regulatory Affairs Department will maintain pertinent information in a database and produce periodic reports for the faculty upon request.

EXHIBIT C
External Activity Review Form
(For Faculty Agreements/Contracts)

Faculty Name _____ Dates of Agreement: _____ to _____

Company/ Sponsor: _____ Total/ Max. Amount of Agreement: _____

Type of Activity: Presentations _____ Consulting _____ Advisory Board _____ Other _____

Nature of Activity:

If speaking, will there be Visual Aides? (Y or N) _____ (If yes, provide to Melissa Polk for review)

If yes, who will prepare: _____

Who will determine the format: _____ What is the format: _____

Who determines content of questions: _____

Describe role in content determination:

Time Commitment Required: (hours per month) _____ Recurrent _____ One Time _____

_____ Travel (Y or N)

Estimated Travel Expense? _____

Who will pay travel expenses? _____

Will any NJH resources be required to complete this activity? If yes, please describe.

Do you expect this activity to generate any Intellectual Property? Yes _____ No _____

Do you currently perform clinical trials for this sponsor? Yes _____ No _____

Are you discussing any future research activities or clinical trials with this sponsor? Yes _____ No _____

Does the sponsor currently fund research in your lab? Yes _____ No _____

} If yes, signature of
TT Office is
required

} If yes, signature
of VP, Legal &
Regulatory or
designee is
required

Signatures:

Signature of Faculty: _____

Signature of Division Head/ Dept. Chairman: _____

Signature of Tech Transfer Office (if necessary): _____

Signature of VP, Legal and Regulatory: _____

EXHIBIT D
Research Review Procedures

A. Financial Conflict of Interest - Determination Pathway

Below is a summary of the process that will be used to determine if an FCOI is present, as more fully described in the remainder of Exhibit D below.

1. Does the disclosed interest require review (see Exhibit D. Section.B.1.)? If yes:↓
2. Is the disclosed interest related to the research (see Exhibit D. Section.B.2.)? If yes:↓
3. Could the interest directly and significantly affect the design, conduct, or reporting of the research (see Exhibit D. Section.E.2)? If yes:↓
4. An FCOI is present and must be managed (and, where appropriate, reported).

B. NJH Review of Disclosures and Relatedness Determination

1. Interests that require review

NJH is responsible for reviewing any disclosures of (i) Significant Financial Interests belonging to an Investigator, the Investigator's spouse, or the Investigator's dependent children, to the extent that they either reasonably appear to relate to the Investigator's Institutional Responsibilities or (ii) Investigator reimbursed or sponsored travel. NJH may, in its discretion, identify through procedures or other guidance documents additional interests that qualify as interests that must be reviewed.

2. Relatedness Determination

Each SFI requiring review will be evaluated to determine whether it relates to the Investigator's research. A SFI will be found to **relate to** the Investigator's research when it is reasonably determined that the SFI could be affected by the research, or is in an entity whose financial interest could be affected by the research. The Investigator may be asked to provide information to assist in the assessment of whether a SFI is related to the Investigator's research.

3. Timing of Review

a. Initial Review of SFI

SFI disclosed at the time of application will be evaluated prior to the initiation of the research activities.

b. Updated Review of SFI

To the extent a new SFI is disclosed to NJH in the course of an on-going research project (i.e., an Investigator who is new to participating in the research discloses a SFI or an existing Investigator discloses a new SFI), NJH will, within a reasonable period of time not to exceed sixty (60) days from the date of the disclosure: (i) determine if the SFI relates to the Investigator's research; (ii) if it relates, determine if it qualifies as an FCOI (pursuant to E below); and (iii) if it is an FCOI, implement on at least an interim basis a management plan in accordance with Section 13.F below. NJH may, depending on the circumstances,

conclude that additional interim measures are necessary with regard to the Investigator's participation in the research between the date of disclosure and the completion of NJH's review.

D. NJH Determination of FCOI

1. Evaluation of Related SFI

NJH will evaluate each SFI that is found to relate to an Investigator's research to make a reasonable determination whether an FCOI exists.

2. FCOI Standard

An FCOI will be found to exist when a SFI related to the Investigator's research could directly and significantly affect the design, conduct, or reporting of the research.

3. FCOI Process and Criteria

NJH maintains a process and criteria for making FCOI determinations. The process and criteria applied will be subject to on-going evaluation and revision as appropriate.

4. Reporting FCOIs in PHS-Funded Research

If the research is externally funded, the identified FCOI must be reported to the sponsor as required by law, regulation, contract or policy.

E. Management of FCOI

1. Management of FCOI

For any identified FCOI, NJH will take appropriate action to manage the conflict in order to reduce the potential for it to compromise the safety or validity of the research. Research in which an Investigator is found to have an FCOI will not be permitted to proceed until the Investigator has agreed to implement an acceptable management plan. The appropriate techniques identified by NJH to manage an identified FCOI will be outlined in a written management plan. Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:

- a. Public disclosure of the FCOI (e.g., when presenting or publishing the research).
- b. For research involving human subjects, disclosure of the FCOI directly to participants.
- c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI.
- d. Modification of the research plan.
- e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
- f. Reduction or elimination of the financial interest (e.g., sale of an equity interest).
- g. Severance of relationships that create FCOI.

2. Disclosure for Drug/Device Research

In any case of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment that has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by NJH, the Investigator will be required to disclose the FCOI in each

public presentation of the results of the research and to request an addendum to previously published presentations.

3. Management of Other Interests

When a disclosed interest does not require review or a SFI is determined not to constitute an FCOI, NJH may nonetheless determine that some type of management or oversight of the interest is appropriate before certain research activities may proceed. NJH may develop additional procedures and/or guidance regarding these types of interests and any associated limitations or requirements.

4. Compliance with Management Plans

Investigators have an on-going obligation to adhere to an imposed management plan and failure to do so may be grounds for sanctions under this Policy.

F. Retrospective Reviews; Mitigation Reports

1. Identification of FCOI Not Timely Disclosed or Reviewed

In the event that NJH identifies a SFI that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by NJH in accordance with this Policy during an on-going research project, NJH will, within a reasonable time period not to exceed sixty (60) days of identifying such an interest:

- (i) Determine if the interest relates to the Investigator's research;
- (ii) If it relates, determine if it qualifies as an FCOI; and
- (iii) If it is an FCOI, implement on at least an interim basis a management plan in accordance with Exhibit D Section E of this Policy to manage the FCOI going forward. Depending on the nature of the FCOI, if a retrospective review for bias is required pursuant to Section 2 below, NJH may determine that additional interim measures are necessary with regard to the Investigator's participation in the research between the date that the FCOI is determined and the completion of NJH's retrospective review.

2. Retrospective Review for Bias

Whenever NJH identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, including but not limited to an Investigator's failure to disclose an SFI that is determined to be an FCOI, or failure by an Investigator to materially comply with a management plan for an FCOI, was not previously reviewed by NJH during an ongoing research project (e.g., was not timely reviewed or reported by a subrecipient), CCO shall, within sixty (60) days: review the SFI; determine whether it is related to research; determine whether an FCOI exists; and, if so: The CCO will refer the matter to the CCC, who will complete a retrospective review of the Investigator's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research, within one hundred twenty (120) days of NJH's determination of non-compliance. Any FCOI report submitted with respect to such research will be updated as necessary in light of the results of the retrospective review.

3. Documentation of Retrospective Review

In all cases where a retrospective review is required NJH will document all required information as required by law, regulation, contract or policy.

4. Mitigation Report

If bias is found in the design, conduct or reporting of any research during the period of noncompliance, NJH will prepare a mitigation report to include, at a minimum, a description of the impact of the bias on the research project and NJH's plan of action or actions taken to eliminate or mitigate the effect of the bias.

5. Reporting

In all cases of FCOI non-compliance NJH will make the appropriate report to the sponsor as required by law, regulation, contract or policy.