I. INTRODUCTION

The Albert Einstein College of Medicine of Yeshiva University (“Einstein”), one of the nation’s premier institutions for medical education, basic research, and clinical investigation, is committed to ensure that all members of the academic community fulfill their Institutional Responsibilities at the highest level of ethical conduct, free of Conflict of Interest.

In addition to medical education, a central academic activity of Einstein is discovery, development, and application of new knowledge intended to improve health. In 1980 the United States Congress passed legislation both to facilitate that process and to permit academic institutions and scientists to benefit financially if their federally sponsored research led to commercial products or uses. During the past decade this legislation has stimulated an increasing collaboration between academic scientists and industries concerned with the development of biomedical products. Federal regulations to assure objectivity in research and to mitigate conflict of interest were published and have been recently revised.\(^1\) In addition, societal concerns about conflict of interest with respect to medical education and patient care have been increasing, and have resulted in serious public attention to these matters.

Einstein has taken a leadership position on Conflict of Interest by promulgating up-to-date policy statements and disclosure requirements. This revised Conflict of Interest Policy is intended to be responsive to expressed societal concerns, and to be compliant with recently revised regulations. It also is intended to assure professional autonomy and academic freedom for Einstein’s scientists, educators, clinical practitioners, students and staff; privileges inherent in the self-regulation of science, medical education, and clinical practice.

II. GENERAL STANDARD

All members of the academic community must exercise sound judgment, good faith, care, and diligence, in all matters relating to the fulfillment of their Institutional Responsibilities and their participation in the academic programs and activities of Einstein. This responsibility includes, but is not be limited to, objectivity, balance, independence, transparency and scientific rigor in the acquisition and interpretation of research data, in the promulgation of medical knowledge and skill, and through evidence-based clinical practice.

In discharging their Institutional Responsibilities on behalf of Einstein, all covered individuals shall act in the best interests of Einstein, its students and its patients. Covered individuals shall refrain from using their positions at Einstein, or knowledge gained from their positions, for inappropriate personal advantage. Furthermore, the judgment and independence of covered individuals in the discharge of their duties and responsibilities on behalf or Einstein must not be impaired, or appear to have been impaired, because of any personal or financial interest or relationship they may have or any activity in which they may engage.

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\(^1\) Federal Register 76:8/25/2011; Department of Health and Human Services; 42CFR part 50 pp. 53256-53293.
An essential element of this policy is to ensure that the integrity of all academic activities at Einstein will in no way be compromised by past, current, and/or anticipated relationships between the covered individuals or the institution and any other enterprise. At the same time, it is expected that properly monitored and regulated relationships will allow Einstein to more effectively pursue new knowledge in the biomedical sciences, and to facilitate the transfer of such knowledge to the care of patients and to the promotion of public health.

III. COMPREHENSIVE POLICY

This document is intended to serve as Einstein’s comprehensive policy statement with respect to Conflict of Interest in all aspects of institutional function. Policy statements pertaining to specific issues of concern are attached and constitute integral parts of this comprehensive policy.

IV. DEFINITIONS:

- **Conflict of Interest (COI):** A Conflict of Interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.

- **Covered Individuals:** This policy applies to all individuals employed by Einstein (through its institutional parent, Yeshiva University), individuals employed by clinical affiliates of Einstein when participating in Einstein’s academic programs and activities, students involved in Einstein’s academic programs and activities, and any other individual (“Staff”), regardless of faculty appointment or employment status, when they are participating in the academic programs and activities of Einstein.

  - **Faculty:** An individual who has an academic appointment in any academic department of Einstein and is listed on Einstein’s faculty rosters, regardless of the institution by which they may be employed, or with which they may be affiliated for purposes of clinical practice. With respect to PHS-funded research, faculty may include:
    
    * **Investigators:** “The project director or principal investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research … or proposed for such funding, which may include, for example collaborators or consultants.”
    * **Senior/key personnel:** “Any person identified as senior/key personnel … in a grant application, progress report or other report.”

  - **Staff:** An individual who does not hold a faulty appointment but who participates in Einstein-related academic programs and activities. With respect to PHS-funded research, Staff may include “Senior/key personnel”.

  - **Students:** Undergraduate medical students and graduate students in the basic and clinical sciences enrolled in Einstein; students enrolled in other educational institutions while on academic assignment at Einstein whether required or elective; residents and fellows enrolled in graduate medical education programs under the sponsorship of Einstein or its clinical affiliates.

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2 These definitions are intended to be consistent with those promulgated in 42CFR Part 50 as published in the Federal Register, 76, August 25, 2011, pp. 53283-53284

3 Institute of Medicine, Conflict of Interest in Medical Research, Education, and Practice, Lo, B and Field, MJ eds. 2009, National Academies Press, Washington, DC., Pp. 45-46

• **Financial Conflict of Interest (FCOI):** A Significant Financial Interest (SFI…see below) that could directly and significantly affect the design, conduct or reporting of research, or otherwise affect a covered individual’s institutional responsibilities.

• **Institutional Official:** The individual designated by Einstein to oversee implementation and management of the COI Program. This individual shall serve as COI compliance officer for Einstein.

• **Institutional Responsibilities:** A covered individual’s professional responsibilities on behalf of Einstein, including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and/or service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

  o **Primary Interests:** In the academic medical center, primary interests include quality of teaching, integrity of research and the welfare of patients. These correspond to the term “Institutional Responsibilities” as defined above.

  o **Secondary Interests:** Secondary interests include not only financial gain, but also the desire for professional advancement, recognition for professional achievement and favors to friends and family, students and colleagues.

• **Significant Financial Interest (SFI):** Any financial interest of a Covered Individual (or of a Covered Individual’s spouse or dependent children) consisting of one or more of the following, that reasonably appears to be related to the Covered Individual’s institutional responsibilities:

  o **Any publicly traded entity:** 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;

  o **Any non-publicly traded entity:** 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 the Covered Individual (or the Covered Individual’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);

  o **Intellectual Property Rights (IP) (e.g., patents, copyrights), upon receipt of income related to such rights or interests.**

**Significant Financial Interest (SFI)** does not include the following types of financial interests: salary, royalties, or other remuneration paid by Einstein to the Covered Individual if the Covered Individual is currently employed or otherwise appointed by Einstein, including intellectual property rights assigned to Einstein and agreements to share in royalties related to such rights; income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, or an institution of higher education⁵, or income from service on advisory committees or review panels for a federal, state, or local government agency, or an institution of higher education.

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⁵ As defined in 20 U.S.C. 1001(a)
V. IMPLEMENTATION

- **Conflict of Interest Committee**

The Conflict of Interest Committee (COIC) is composed of a balanced representation of the clinical and pre-clinical faculties and includes ex-officio representatives of the Einstein’s academic administration, and of the administration of Einstein’s major clinical affiliate(s), all appointed by the Dean.

- **Conflict of Interest Program**

The Chair of the COIC, who shall be appointed by the Dean, serves as Director of Einstein’s Conflict of Interest Program and is the Institutional Official for all COI matters.

The Director of the COI Program shall establish a database for all COI information. This shall be maintained in a confidential manner.

The Director of the COI Program shall establish and maintain a page on the Einstein web-site that is publicly accessible. As required by federal regulation, Einstein’s COI Policy, and a roster of faculty with identified FCOI shall be posted on this web-page.

VI. SCOPE and JURISDICTION

- **The Institution**

It is recognized that the Institution (Einstein \textit{per se}) may have potential FCOI when its financial interests might be affected or reasonably appear to be affected by the outcomes of a research study. To mitigate that possibility, the following has been implemented:

  o Oversight of research, technology transfer agreements, intellectual property rights, and Conflict of Interest matters, are all managed outside of the academic and financial administrative offices of Einstein.

  o As required to mitigate possible Institutional COI, review of protocols for human subjects protections purposes will be obtained using an external IRB.

- **Institutional Governance**

Yeshiva University has promulgated a Conflict of Interest Policy for Yeshiva University Boards, Committees and Officers, which serves as the COI policy pertaining to institutional governance of all constituent schools including Einstein.

- **Administration**

Policies and procedures pertaining to purchasing and procurement, and to non-faculty employees of Einstein have been published.

\footnote{Ibid. pg. 53287}
• Academic Programs

All academic programs and activities conducted at Einstein, sponsored by Einstein, using the Einstein name, or utilizing any Einstein facilities are subject to this comprehensive policy. Such academic programs include: basic, clinical and translational research; premedical, undergraduate, graduate, and continuing medical education; and graduate education in basic and clinical sciences.

- Research

All research conducted under the auspices of Einstein is subject to requirements of this policy. Of particular concern is research involving human subjects in any way. For that reason, Einstein’s Institutional Review Board comprising East Campus-based (Einstein) and West-Campus-based (Montefiore) review committees has established a detailed, joint policy on conflict of interest.

- Education

Faculty must ensure objectivity, balance, independence, transparency, and scientific rigor in all student educational activities. All teaching Faculty (and any Staff involved in teaching), whether participating as lecturers or preceptors for basic science courses, or as instructors in clinical programs are expected to disclose significant financial relationships relevant to their teaching responsibilities and to assist in resolving any conflict of interest that may arise from any such relationship. Presenters must also make a meaningful disclosure to the audience of their discussions of unlabeled or unapproved uses of drugs or devices.

- Clinical Practice

In collaboration with Montefiore Medical Center, Einstein has adopted a Policy the Montefiore policy on Pharmaceutical and Medical Device Vendor Relationships with Clinical Programs, which shall pertain to the small set of clinical programs operating under the auspices of Einstein (CERC, DOSA, and Soundview Throgs Neck Community Mental Health Center).

The substantial majority of clinical practice programs related to the Albert Einstein College of Medicine are owned and operated by Einstein’s clinical affiliates. It is the expectation of Einstein that each affiliate will establish and maintain appropriate policies pertaining to conflict of interest in clinical practice. In particular, such policies must address the status and behaviors of Medical Vendor Representatives. The policy established by Montefiore Medical Center is attached.

• Conflict of Commitment

The participation of covered individuals in external activities that enhance their professional skills and constitute public service can be beneficial to Einstein as well as the individual. External activities provide an opportunity to discover and pass on knowledge, with the formation of alliances that enhance the university’s academic and research missions. Covered individuals are, therefore, encouraged to participate and provide leadership in professional organizations, panels, committees, and other broadly defined public and professional service opportunities. These interactions can enhance relationships with a wide variety of governmental, business and not-for-profit entities that enhance the Einstein’s teaching and research missions.
External activities, however, can lead to conflicts of commitment with regard to an individual’s Institutional Responsibilities, or to the misuse of institutional resources. It is Einstein policy that covered individuals are expected to devote their academic work activities to official functions of Einstein, and to use Einstein-derived resources only in the interest of the College of Medicine. Einstein resources may not be committed to external activities not in the interest of the College. As such, this policy is intended to alert covered individuals to the recognition of conflicts of commitment, and to Einstein’s Policy on Outside Professional Income.

VII. PROCEDURES

- Disclosure by Covered Individuals

All covered individuals must disclose any significant financial interest as defined above and any other activity or association that might constitute a conflict of interest relevant to their institutional responsibilities. Full disclosure and review of possible conflict of interest situations is intended to provide assurance to covered individuals, to Einstein, and to the public that such outside business relationships have been examined, and will be conducted in a manner consistent with institutional and public values and policies. A disclosure form must be submitted under the following circumstances:

- At time of initial appointment to Einstein;
- Annually thereafter;
- Whenever circumstances arise that may either:
  - Constitute a new conflict of interest, or
  - Change the facts applicable to a previously disclosed potential conflict.
- Such a report must be filed within 30 days of the change of circumstance;
- As teaching faculty in a course or clerkship.\(^7\)
- Upon submission of a human subject research protocol or progress report for a clinical research project in which they are an active participant. This shall include recruitment bonuses paid for human subject research participants or for reaching an accrual goal within a specific time frame, as well as being offered a finder’s fee for referral of potential research subjects.
- Upon submission of grant application to the Office of Grant Accounting as required by the funding or reviewing agency or other governmental agencies. This includes compliance with PHS and FDA requirements.
- Upon appointment as a member of the Institutional Review Board (IRB), the Committee on Conflict of Interest, or the Patent Committee;
- Upon submission of a contract for industry-sponsored research.
- Upon establishment of a contract with a commercial entity as detailed by Einstein’s Offices of Biotechnology and Business Development.\(^8\)

\(^7\) Faculty disclosures will be available as part of the course description. See attachment #5
\(^8\) <http://www.einstein.yu.edu/administration/biotechnology-business-development/default.aspx?id=28485&ekmensel=15074e5e_4066_4073_btnlink>

updated on 9/20/2012 by L. Hall-Pearson
Individuals completing the disclosure form must take reasonably diligent steps to determine the scope of their actual and potential interests as they may represent significant secondary interests with respect to their institutional responsibilities.

To the extent that the disclosure form requires information about actual or potential interests of an individual’s spouse or dependent children, there is no requirement to undertake any additional fact-gathering, but only report what is already known.

In general, if there is uncertainty as to whether information is responsive to a question, it is better to err on the side of reporting. It shall be the responsibility of Einstein’ Committee on COI to determine whether any disclosed interest actually represents a financial conflict of interest or conflict of commitment with respect to an individual’s institutional responsibilities.

Individuals required to complete a disclosure form will receive electronic notification when this must be done. The form must be completed and submitted within 10 business days of that notification.

- **Travel**: Covered Individuals must also disclose any reimbursed or sponsored travel related to their Institutional Responsibilities. This requirement does not apply to travel that is reimbursed or sponsored by any federal, state or local government agency, any institution of higher learning, and academic teaching hospital, a medical center, or research institute that is affiliated with an institution of higher learning.

  - Travel reimbursement disclosure must include (at a minimum):
    - The purpose of the trip,
    - The identity of the sponsor/organizer,
    - The destination,
    - The duration.

  - The Institutional Official shall determine whether additional information is required to appropriately evaluate a travel disclosure.

- **Management of Disclosed Information**

In addition to individual disclosure by covered individuals, disclosure of possible COI may occur in the following circumstances:

  - With respect to grant funded research: any interest that the Institution identifies as conflicting subsequent to the Institution’s initial report under the award, must be reported to the PHS Awarding Component and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within sixty days of that identification.

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9 Federal Register, 76, August 25, 2011 pg. 53284
If the failure of an Investigator to comply with the conflict of interest policy of the Institution has biased the design, conduct, or reporting of the PHS-funded research, the Institution must promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the funded project.

The Conflict of Interest Committee will maintain records of all FCOI, and of all actions taken by the Institution to mitigate or eliminate any such conflicting interest for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations.

The COI Committee will establish a mechanism to promptly review all COI disclosures, to identify those which may indicate potential conflict of interest, and to define measures appropriate to manage identified COI situations.

All COI disclosures will be evaluated by a COI screening committee, comprising the COI Committee chair, two administrative members and a faculty member of the COI committee.

- The screening committee shall be empowered to determine whether or not an impermissible conflict of interest exists, provided that such determination must be by unanimous agreement.
- If the screening committee determines that an impermissible COI exists, it shall, within 7 days, make a recommendation as to the actions appropriate to eliminate or adequately mitigate the conflict.
- The covered individual shall receive a written explanation and justification of the basis for such recommendations.
- The covered individual may respond either in writing or in person to the determination and/or recommendations of the screening committee.

In the event that the screening committee is unable to reach a unanimous determination, or in the event that a covered individual may disagree with the determination and/or recommendations of the screening committee, the matter shall be referred to the full COI Committee. The full Committee shall establish a final determination as to whether an impermissible COI exists and shall define requirements for its mitigation as appropriate.

Upon receipt of a decision of the Conflict of Interest Committee, the covered individual may, within thirty (30) days, submit new and relevant information that could effect the decision rendered, and may request reconsideration of the decision by the Committee.

The Committee shall provide a prompt and thorough review of such documentation and decide whether the initial decision should be implemented, or whether modification of the decision is warranted.

In the event that an impermissible conflict of interest is identified, the Committee on Conflict of Interest will report its findings and recommendations for the management and/or mitigation of the conflict to the Dean, with copies, as appropriate, to the Executive Dean, the Covered Individual’s Department Chairman, and to the IRB (if related to human research), research sponsors, and governmental agencies as they may be involved in the matter.
When the Conflict of Interest Committee determines that any reported activity is restricted or prohibited, the individual(s) must promptly comply with any directives for monitoring, modification or termination of such activity.

Even where a conflict of interest situation is deemed allowable, the conflict may need to be disclosed to government or private agencies that are sponsoring or considering sponsoring the research.

It may also be necessary to disclose the conflict of interest to journals, professional meeting, or other public setting in which results relevant to the conflict of interest are presented.

In addition, if any reported activity is related to a human subject research protocol, disclosures to potential subjects must be made in accordance with directives from the Committee on Clinical Investigations.

As required by federal regulations, a roster of individuals with identified FCOI related to PHS-funded research will be posted on the COI web-page.

**SANCTIONS FOR NON-COMPLIANCE**

Einstein expects all covered individuals to fully comply with this policy. A knowing or deliberate breach of policy, including failure to file or to knowingly file an incomplete, erroneous, or misleading disclosure form, or failure to comply promptly with prescribed monitoring, modification or termination requirements will subject the involved faculty member to possible sanctions. In such instances where the continuance of the individual in his/her duties threatens immediate harm to themselves or others, or may cause irreparable damage to Einstein, a person against whom written charges have been made may be suspended from all or some duties by the Dean pending final action on such charges. In the case of a faculty member such suspension by the Dean could be with salary pending final action upon such charges.

The procedures described herein shall supersede Sections 5.03 and 5.04 of the Rules and Regulations Providing for a System of Appointments, Titles and Compensation Arrangements of the Albert Einstein College of Medicine of Yeshiva University. The COI Committee is charged with the responsibility to review all instances of non-compliance with this policy and to recommend appropriate sanctions to the Dean. Included in possible sanctions are the following:

- Formal admonition including possible inclusion in the individual’s file of a letter indicating that the individual’s good standing has been called into question;

- Ineligibility of the individual to apply for grants, sponsored research agreements, to seek Committee on Clinical Investigation (CCI) approval, conduct animal or other research, or to teach or supervise students;

- Notice to appropriate parties (including government agencies or otherwise) of the conflict of interest activity found to exist;

- Dismissal from the College of Medicine.

**NON-RETALIATION**

No individual will be subjected to retaliation by the College, or by individuals under its direction or control, for good faith reporting of any actual or perceived violation of the requirements in this policy.
REQUESTS for INFORMATION

The Albert Einstein College of Medicine will respond to requests for information pertaining to financial conflicts of interest as required by 42CFR Part 50 subpart F. Any such request must include the name of a specific senior/key person, and the name or identifying number of the PHS-funded research project about which the request is being submitted.

Requests must be submitted in writing. A response will be sent within 5 business days of receipt by the Chair of the Conflict of Interest Committee.

Address requests for information to:

Michael J. Reichgott, MD, PhD
Chair, Conflict of Interest Committee
Albert Einstein College of Medicine
1300 Morris Park Avenue
Belfer 1003A
Bronx, NY 10461