



Comprehensive Conflict of Interest Policy

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I. Purpose

The Albert Einstein College of Medicine (“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. 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. Federal regulations to assure objectivity in research and to mitigate conflict of interest have been published.¹

Einstein has taken a leadership position on Conflict of Interest by maintaining up-to-date policy statements and disclosure requirements. This Comprehensive Conflict of Interest Policy is intended to be responsive to expressed societal concerns, and to be compliant with federal 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. Scope

II.A. 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.

II.B. Covered Individuals

This policy applies to all individuals employed as faculty by Einstein, who are appointed to the Einstein faculty but are on the payroll of other institutions, or whose grants are awarded to Einstein. (Covered Individuals).

¹ Federal Register 76:8/25/2011; Department of Health and Human Services; 42CFR part 50 pp. 53256-53293.

II.C. The Institution

It is recognized that Einstein may have potential conflict of interest when its financial interests might be affected or reasonably appear to be affected by the outcomes of a research study being conducted in its facilities and/or by its faculty. To mitigate that possibility, the following has been implemented:

- 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 (the “Dean’s Offices”) of Einstein.
- As required to mitigate possible Institutional COI, protocols in which Einstein might have a potential financial interest will be reviewed, for human subjects’ protection, using an external IRB.

II.D. Institutional Governance

Einstein is a constituent division of the Montefiore Medicine Academic Health System (“Montefiore”). Montefiore has established a Conflict of Interest Committee at Einstein, which implements COI policy pertaining to Einstein’s Academic Programs.

II.E. Administrative COI Management

Einstein adheres to policies and procedures pertaining to [purchasing and procurement](#), and to oversight of potential COI for non-faculty employees have been published by Montefiore.

II.F. Academic Program COI Management

All academic programs 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.

II.F.1. Research

All research conducted under the auspices of Einstein is subject to requirements of this policy. Of particular concern is research involving human subjects. For that reason, Einstein’s Institutional Review Board (IRB) comprising East Campus-based (Einstein) and West-Campus-based (Montefiore) review committees require that all submitted protocols, amendments and annual progress reports undergo COI review before being accepted for IRB review.

II.F.2. 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 any financial relationships that may be related to their teaching responsibilities and to assist in resolving any conflict of interest that may arise from any such relationship. Presenters must make a

meaningful disclosure to the audience at the time of presentation if their presentation includes discussion of unlabeled or unapproved uses of drugs or devices.

II.F.3. Student Stipends and Awards

Albert Einstein College of Medicine prohibits the provision of industry funding directly to medical students to support clinical or research fellowships or to attend conferences or training events. Students may apply for industry-supported fellowships or grants and may compete for industry-supported prizes by submitting applications to a committee of faculty which will identify applicants to represent the College. Einstein will receive and administer any awards. All funding for students to conduct scientific research and for related activities is provided through Einstein's Student Research Program.

II.F.4. Clinical Practice

As a constituent division of Montefiore, Einstein adheres to the published Montefiore [policy on Pharmaceutical and Medical Device Vendor Relationships with Clinical Programs](#).

With respect to clinical practice programs owned and operated by Einstein's other clinical affiliates in which Einstein-sponsored academic activities may take place, 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 as they related to students and trainees in undergraduate and graduate medical education programs sponsored by Einstein.

II.G. 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](#).

NB. Einstein does not permit acceptance of recruitment bonuses paid for the identification or referral of human subject research participants for reaching an accrual goal for a clinical trial within a specific time frame.

III. Policy

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.

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.A. Implementation

III.A.1. 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.

III.A.2. 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. Einstein's comprehensive COI policy and related documents shall be posted on this website. [<http://www.einstein.yu.edu/administration/conflict-of-interest/>].

- As required by federal regulation,² Einstein shall ensure public accessibility by responding, within 5 business days, to a written request for information concerning the commercial interests of any Covered Individual as they might pertain to a specifically identified research project or protocol.

III.B. Procedures

III.B.1. Disclosure by Covered Individuals

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 commercial relationships have been examined and will be managed in a manner consistent with institutional and public values and policies. Notwithstanding federal definitions (see below), Einstein requires disclosure of commercial relationships of any dollar value/amount with not-excluded entities.

Covered Individuals must disclose, at the time of appointment or hiring and at designated times (“events”) thereafter (as defined below) all relationships, regardless of dollar value or amount and in particular any such relationships that meet the federal definition of “significant financial interests” (SFI), with all external commercial entities as defined in federal regulations. Subsequent events which require up-dated disclosure include:

- Upon submission of a human subject research protocol, amendment, or progress report for a clinical research project in which the faculty member is an active participant.
- 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 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](#).
- Upon appointment as a member of the Institutional Review Board (IRB), the Committee on Conflict of Interest, or the Patent Committee.

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

² CFR 50.605(a)(5)(i)

represents a financial conflict of interest or conflict of commitment with respect to an individual's institutional responsibilities.

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

III.B.2. Exclusions from Required Disclosure

Exclusions from required disclosure include:

- Income from investment vehicles (mutual funds/retirement accounts) as long as the individual does not directly control investment decisions made in these vehicles.
- Income from seminars, lectures, or teaching engagements sponsored by federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or
- Income from service on advisory committees or review panels for a federal, state or local government agency, institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

III.B.3. Disclosure of Travel³

Covered Individuals must disclose any travel related to their institutional responsibilities that is reimbursed or sponsored (i.e., not reimbursed, but paid on behalf of the Individual so that the exact monetary value may not be readily available) by a not-excluded entity. As noted above, excluded entities include federal, state, and local government agencies, institutions of higher education, academic teaching hospitals and medical centers, and research institutes that are affiliated with an institution of higher education.

- A covered individual's initial disclosure must include any reimbursed or sponsored travel that was received within the prior 12 months.
- Any sponsored or reimbursed travel occurring subsequent to the initial disclosure must be reported within 30 days of the travel event.
- Travel reimbursement disclosure must include (at a minimum):
 - The purpose of the trip,
 - The identity of the sponsor/organizer,
 - The destination,
 - The duration.

³ Federal Register, 76, August 25, 2011 pg. 53284

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

III.B.4. Timeliness of Disclosure

- Covered Individuals must submit an updated disclosure within thirty (30) days of establishing a new commercial relationship, receiving new remuneration in an existing relationship, or a travel event as described above.
- A disclosure is considered to be “up-to-date” if it is dated within 6 months of the date of Conflict of Interest review.

III.B.5. COI Committee Action

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 undergo preliminary screening by the COI administrator and COI Director.
 - This preliminary screen may determine that no impermissible COI exists, or that a possible COI can be mitigated by disclosure in a consent form or at time of publication or presentation.
 - If the preliminary screening determines that an impermissible COI may exist and may require more extensive mitigation, the matter shall be referred to the full committee for its review and recommendation. Such referral may be accomplished electronically.
 - The committee 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 a covered individual may disagree with the determination and/or recommendations of the initial screening committee, s/he may discuss the disagreement with the COI Director. If resolution is not achieved, the matter shall be referred to the full COI Committee. The full COI Committee shall establish a final determination and shall define requirements for its mitigation as appropriate.
- Upon receipt of a decision of the COI Committee, the covered individual may, within thirty (30) days, submit new and relevant information that could affect 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.
- In any case in which the HHS determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution as required by this regulation, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

III.B.6. Reporting FCOI Pertaining to PHS-Funded Research

In the event that a FI or SFI is identified as a financial conflict of interest (FCOI) with respect to a PHS-funded research project, an FCOI report shall be provided to the PHS Awarding Component, as required by federal regulations.⁴

- 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.
- 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.

⁴ 42CFR 50.605(b) Reporting of financial conflicts of interest. FR 76:165 pg. 53287 August 25, 2011

III.B.7. Sub-Recipients⁵

For any research in which there is a sub-recipient relationship with an investigator at another institution, Einstein shall incorporate as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of Einstein or that of the subrecipient will apply to the subrecipient's Investigators.

- If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy the subrecipient shall certify as part of the written agreement that its policy complies with federal regulation. The written agreement shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to Einstein, and such time period(s) shall be sufficient to enable Einstein to provide timely FCOI reports, as necessary, to the PHS.
- If the subrecipient cannot provide such certification, the written agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of Einstein for disclosing significant financial interests that are directly related to the subrecipient's work for Einstein. The written agreement shall specify time period(s) for the subrecipient to submit all disclosures of significant financial interests to Einstein, and such time period(s) shall be sufficient to enable Einstein to fulfill its timely review, management, and reporting obligations under federal regulation.

III.B.8. Monitoring

Whenever a COI management plan has been implemented, the COI committee shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the research project. If funding lapses, Einstein will continue to monitor any involved study until its completion to ensure that COI requirements have been met.

III.B.9. Retrospective Review

As required by federal regulation,⁶ in the event that the COI Committee identifies a FI or SFI that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the COI Committee shall, within sixty days: review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so:

- Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward; and

⁵ 42 CFR 50.604(c)

⁶ CFR50.605(a)(3)

- Shall, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
- Einstein will document the retrospective review. Such documentation will include, but not necessarily be limited to, all of the following key elements:
 - Project number
 - Project title
 - PD/PI or contact PD/PI if a multiple PD/PI model is used
 - Name of the Investigator with the FCOI
 - Name of the entity with which the Investigator has a financial conflict of interest
 - Reason(s) for the retrospective review
 - Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed)
 - Findings of the review
 - Conclusions of the review
- Based on the results of the retrospective review, if appropriate, the Institution shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward.
- If bias is found, the Institution is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include the key elements documented in the retrospective review, a description of the impact of the bias on the research project, and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias. (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, Einstein will submit FCOI reports annually.
- Depending on the nature of the FCOI, Einstein may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of Einstein's retrospective review.

III.B.10. Records Maintenance

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.⁷

⁷ CFR 50.605(A)(5)(IV)

- Einstein shall submit annual FCOI reports pertaining to PHS-funded research as required by federal regulations.
- Prior to the expenditure of any funds under a PHS-funded research project, Einstein shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting and ensure that a management plan has been implemented.

III.C. 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 covered individual 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. 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.

III.D. 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.

III.E. PUBLIC ACCESSIBILITY

In compliance with federal regulations⁸, the Albert Einstein College of Medicine shall ensure public accessibility by responding, within 5 business days, to a written request for information concerning any significant financial interest disclosed to the institution that meets the following criteria:

- a. The FI or SFI was disclosed and is still held by the investigator;
- b. Einstein has determined that the FI or SFI is related to PHS-funded research; and
- c. Einstein has determined that the FI or SFI is an FCOI.

Any such request must include the name of a specific investigator, 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. Information concerning significant financial interests of an individual shall remain available, for responses to written requests, for three years from the date that the information was most recently updated. 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
Belfer 301, 1300 Morris Park Avenue
Bronx, NY 10461

IV. Definitions

Academic Programs: The Academic Programs of Einstein include: undergraduate medical education; graduate medical education; graduate education in the biomedical sciences; and clinical, translational, basic science, and health policy research.

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.⁹

Covered Individuals: This policy applies to all individuals employed by Einstein, individuals employed by clinical affiliates of Einstein when participating in Einstein's Academic Programs, students involved in Einstein's Academic Programs, and any other individual ("Staff"), regardless of faculty appointment or employment status, when they are participating in Einstein's Academic Programs.

⁸ CFR 50.605(a)(5)(i)

⁹ 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

“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:”**¹⁰ “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 personnel⁴:**” “Any person identified as senior/key personnel ...in a grant application, progress report or other report....”

“Staff:” An individual who does not hold a faculty 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.

Financial Conflict of Interest (FCOI): A Financial Interest (FI...for Covered Individuals (defined below)) or Significant Financial Interest (SFI...for Related Party (defined below)) that could directly and significantly affect the design, conduct or reporting of research, or otherwise affect a covered individual’s institutional responsibilities.

Financial Interest (FI): FI exists if the Covered Individual receives **ANY** remuneration from an external entity in the twelve months preceding the disclosure; or holds any equity interest in the entity as of the date of disclosure. 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. **FI** also exists with respect to **Intellectual Property Rights (IP)** (*e.g.*, patents, copyrights), upon receipt of **ANY** income related to such rights or interests

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

¹⁰ 4 Federal Register, 76, August 25, 2011 pg. 53284 col. 1.

practice, institutional committee memberships, and/or service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

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

Medical Vendor Representatives: Individuals employed by a commercial organization that vends products such as drugs, medical devices, equipment used in patient-care, research supplies and/or equipment, information technology, or any other such products that may be ordered, prescribed or used by Einstein faculty or staff.

Related Party: Covered Individual’s spouse, domestic partner, or dependent child.

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

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

Financial Interest (FI) and Significant Financial Interest (SFI) do 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 education¹¹, or income from service on advisory committees or review panels for a federal, state, or local government agency, or an institution of higher education.

V. Effective Date

Effective as of: 28 March 2018

VI. Policy Management and Responsibilities

Einstein's Conflict of Interest department is the Responsible Office under this Policy. Einstein's Associate Dean for Finance and Administration is the Responsible Executive, and Einstein's Director of Conflict of Interest is the Responsible Officer for the management of this policy.

VII. Approved (or Revised)

 _____ Responsible Executive Jed M. Shivers Associate Dean for Finance and Administration	 _____ Date
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¹¹ As defined in 20 U.S.C. 1001(a)