



# 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, and Montefiore Medical Center ("Montefiore") are committed to ensuring 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, the central academic activity of Einstein includes the discovery, development, and application of new knowledge intended to improve health. In 1980, the United States Congress passed legislation to facilitate that process and 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. The Department of Health and Human Services (HHS) has published regulations to promote objectivity in research and to mitigate conflict of interest.<sup>1</sup>

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 is also 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**

### **Comprehensive Policy**

This document is intended to serve as Einstein's comprehensive policy statement concerning 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.

### **Covered Individuals**

This policy applies to all individuals employed as Faculty by Einstein; individuals who are appointed to Einstein Faculty but are on the payroll of other institutions; individuals whose grants are awarded to Einstein; and any other individual (e.g., staff or students), regardless of faculty appointment or employment status, when they are serving as an Investigator on research conducted at Einstein or listed as Senior/key personnel by the Institution on a grant application, progress report, or any other report submitted to the PHS by the Institution.

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<sup>1</sup> 76 Fed. Reg. 53256-53293 (Aug. 25, 2011) (codified at 42 CFR 50; 45 CFR 94).

## Institutional Conflicts of Interest (ICOI)

It is recognized that Einstein and Montefiore may have a potential conflict of interest ("COI") when their financial interests might be affected or reasonably appear to be affected by the outcomes of a research study being conducted in their facilities and/or by their investigators.

Determinations of ICOIs are made by the COI committee (see section III.A below), which includes representatives from Einstein and Montefiore. Management strategies of ICOIs may vary depending on the nature of the conflict and whether the research involves human subjects. Potential management strategies include, but are not limited to, the following:

- Disclosure of the ICOI in the informed consent process
- Disclosure of the ICOI to all members of the research teams and in all publications and presentations
- Use of an external Institutional Review Board
- Use of an independent study monitor or Data and Safety Monitoring Board (DSMB)

## Procurement COI Management

Einstein adheres to policies and procedures pertaining to [purchasing and procurement](#) that Einstein and/or Montefiore have published.

## 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.A.1. Research

All research conducted under the auspices of Einstein and Montefiore are subject to the requirements of this policy. Of particular concern is research involving human subjects. For that reason, Einstein's Institutional Review Board (IRB) requires that all submitted protocols, key personnel and funding amendments, and continuing reviews undergo COI review before IRB approval can be issued.

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

### II.A.2. Education

Faculty must ensure objectivity, balance, independence, transparency, and scientific rigor in all student's educational activities. All teaching faculty, as well as any staff involved in teaching, are required to disclose any financial relationships that may be related to their teaching responsibilities. This applies to those who participate as lecturers or preceptors for basic science courses or as instructors in clinical programs. Additionally, they must assist in resolving any conflict of interest that may arise from such

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

### II.A.3. Student Stipends and Awards

Albert Einstein College of Medicine prohibits the provision of industry funding directly to medical students and other trainees to support clinical or research fellowships or to attend conferences or training events.

### II.A.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](#). For Montefiore Medical Center's clinical COI policy, refer to JH20.1 "Conflict of Interest."

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 relate to students and trainees in undergraduate and graduate medical education programs sponsored by Einstein.

## Conflict of Commitment

The participation of Covered Individuals in external activities that enhance their professional skills and constitute public service can benefit Einstein and 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 Einstein's teaching and research missions.

External activities, however, can lead to conflicts of commitment regarding an individual's Institutional Responsibilities or the misuse of institutional resources. It is Einstein's policy that Covered Individuals are expected to devote their work activities to the 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 that are 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](#).

## Policy

All academic community members must exercise sound judgment, good faith, care, and diligence in all matters relating to fulfilling their Institutional Responsibilities and participating in Einstein's Academic Programs and activities. This responsibility includes but is not limited to, objectivity, balance,

independence, transparency, and scientific rigor in acquiring and interpreting research data, promulgating 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 of 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, adequately monitored and regulated relationships are expected to allow Einstein to pursue new knowledge more effectively in the biomedical sciences and facilitate the transfer of such knowledge to the care of patients and the promotion of public health.

## Implementation

### II.A.5. 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 Einstein and Montefiore's academic administration and of the administration of Einstein's major clinical affiliate(s), all appointed by the Dean.

### II.A.6. Conflict of Interest Program

- The Office of Human Research Affairs (OHRA) shall administer the COIC.
- The Dean appoints the Chair of the COIC.
- The OHRA shall establish a database for all COI information. This shall be maintained in a confidential manner.
- As required by federal regulation,<sup>2</sup> 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.

## Procedures

### II.A.7. Disclosure by Covered Individuals

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<sup>2</sup> 42 CFR § 50.605(a)(5)(i)

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 all commercial relationships, regardless of dollar value or amount, with all external commercial entities. Covered individuals must also disclose any paid or unpaid leadership position in an external entity, such as director, officer, partner, trustee, agent, or any position of management.

Covered Individuals who are engaged in PHS-funded research or any human research are required to submit updated disclosures annually (at minimum).

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.

The following events also require an up to date (within the past 6 months) disclosure on record:

- Upon submission of a human subject research protocol, amendment, or progress report for a human research project, where the Covered Individual serves as an investigator.
- Upon receipt of Just-in-Time request, Notice of Award, or federal subaward agreement, prior to disbursement of funds, 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.

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's Office of Human Research Affairs, in conjunction with Einstein's Committee on COI, to determine whether any disclosed interest represents a financial conflict of interest or conflict of commitment concerning an individual's institutional responsibilities.

#### **II.A.8. 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.

#### II.A.9. Disclosure of Travel<sup>3</sup>

Covered Individuals must disclose any travel related to their institutional responsibilities that are reimbursed or sponsored (i.e., not refunded, 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.

#### II.A.10. COI Education

- Covered Individuals must complete COI training prior to engaging in any human research or PHS-funded research and at least every four years thereafter and immediately when any of the following circumstances apply:
  - An investigator is new to the Institution.
  - An investigator is found to be out of compliance with the Institution's financial conflict of interest policy.
- The OHRA will educate Covered Individuals on any revisions to the Institution's conflict of interest policy or procedures that affect the requirements of Covered Individuals.

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<sup>3</sup> 76 Fed. Reg. 53265 & 53284 (Aug. 25, 2011)

## II.A.11. COI Committee Action

- COI disclosure forms will be maintained in a secure electronic file accessible only by appropriate credentialed individuals.
- The COI disclosure forms submitted by the PI, and all other Investigators listed on a research protocol submission to the Einstein IRB or federal grant application will undergo preliminary screening by COI staff. COI staff may certify that no COI exists for individuals whose disclosure forms do not include any Significant Financial Interests.<sup>4</sup>
- COI disclosure forms that identify any Significant Financial Interest will undergo secondary screening by COI senior staff or leadership to evaluate the significance of the financial interest and its relationship to the proposed research.
- Financial interests unrelated to the proposed research will be designated as no COI.
- Financial interests that are potentially related to the proposed research (e.g., a financial interest in the sponsor of the research or a financial interest in the product or service being tested) will be sent to a designated reviewer to determine if they constitute a COI.
  - Financial disclosures of consulting income up to \$10,000 qualify for administrative COI review by COI staff with the position of Assistant Director or higher.
  - Financial disclosures of consulting income greater than \$10,000, or disclosures of other Significant Financial Interests, require review by a member of the COI committee.
- Financial relationships that meet the SFI threshold and are related to the research comprise a "Financial Conflict of Interest (FCOI)" and shall require a COI Management Plan.
  - Should an FCOI exist, the OHRA will consult with the COIC Chair to determine the most appropriate management plan.
  - The COIC Chair may convene a meeting of the COIC to review appropriate COI management strategies.
- The covered individual shall be notified of the COI management plan. The covered individual deemed to have a COI requiring management may respond in writing, by phone, or in-person to the determination and/or recommendation.
- The full COIC shall establish a final determination and shall define requirements for its mitigation as appropriate.
- When the COIC 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 meetings, or other public settings in which results relevant to the conflict of interest are presented.

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<sup>4</sup> See Section IV for definitions of "Investigators."

- 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.

#### II.A.12. Reporting FCOI Pertaining to PHS-Funded Research

In the event that a 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.<sup>5</sup>

- 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 must be 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, in that case, 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.

#### II.A.13. Sub-Recipients<sup>6</sup>

For any PHS-funded research in which there is a sub-recipient relationship with an investigator at another institution, and Einstein is the prime recipient of the award, 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.

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<sup>5</sup> 76 Fed. Reg. 53286-53287 (August 25, 2011) (codified at 42 CFR § 50.605(6) and 42 CFR § 50.605(c))

<sup>6</sup> 42 CFR § 50.604(c)

- 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.

#### II.A.14. Monitoring

Whenever a COI management plan has been implemented, OHRA, in conjunction with Research Compliance, 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.

#### II.A.15. Retrospective Review

As required by federal regulation,<sup>7</sup> in the event that the COIC identifies an 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 COIC 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
- Shall, within 120 days of the determination of non-compliance, 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 non-compliance, 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

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<sup>7</sup> 42 CFR §50.605(a)(3)

- 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 non-compliance is determined and the completion of Einstein's retrospective review.

#### II.A.16. Records Maintenance

The COIC 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.<sup>8</sup>

- 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.

#### SANCTIONS FOR NON-COMPLIANCE

Einstein expects all Covered Individuals to fully comply with this policy. Failure to comply with prescribed monitoring, modification, or termination requirements or knowingly filing an incomplete, erroneous, or misleading disclosure form constitutes a deliberate breach of policy. Such a breach will result in possible sanctions against the involved covered individual. In such instances where the continuance of the individual in his/her duties threatens immediate harm to themselves or others or may

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<sup>8</sup> 42 CFR §50.605(a)(5)(iv)

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.

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 COIC is responsible for reviewing all instances of non-compliance with this policy and recommending 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 Institutional Review Board (IRB) 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;
- Suspension from some or all duties with or without pay;
- 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.

#### PUBLIC ACCESSIBILITY

In compliance with federal regulations<sup>9</sup>, 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 SFI was disclosed and is still held by the Investigator;
- b. Einstein has determined that the SFI is related to PHS-funded research; and
- c. Einstein has determined that the 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 the 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 reply will be sent within 5 business days of receipt.

**Address requests for information to:**

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<sup>9</sup> 42 CFR §50.605(a)(5)(i)

Office of Human Research Affairs  
Albert Einstein College of Medicine  
1300 Morris Park Avenue, 10<sup>th</sup> Floor  
Belfer Building  
Bronx, New York 10461

## 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 a secondary interest will unduly influence professional judgment or actions regarding a primary interest.<sup>10</sup>

**Covered Individuals:** This policy applies to all individuals employed as faculty by Einstein; individuals who are appointed to Einstein faculty but are on the payroll of other institutions; individuals whose grants are awarded to Einstein; and any other individual (e.g., staff or students), regardless of faculty appointment or employment status, when they are serving as an Investigator on research conducted at Einstein or listed as Senior/key personnel by the Institution on a grant application, progress report, or any other report submitted to the PHS by the Institution.

**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.

**Financial Conflict of Interest (FCOI):** A Significant Financial Interest that could directly and significantly affect research design, conduct, or reporting or otherwise affect a covered individual's institutional responsibilities.

**Financial Interest (FI):** A financial interest or relationship of a Covered Individual (or those of a Covered Individual's Related Party), whether or not the value is readily ascertainable, that reasonably appears to be related to a Covered Individual's responsibilities to the College.

**"Financial Interest" includes:**

- **Any remuneration** from an external entity in the twelve months preceding the 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).

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<sup>10</sup> Lo, B., Field, M.J. (2009). Institute of Medicine. *Conflict of Interest in Medical Research, Education, and Practice*. Washington, DC: National Academies Press. <https://doi.org/10.17226/12598>. pp. 45-46

- **Any equity interest**, excluding ownership in mutual funds or pension funds described below. 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 paid or unpaid leadership position** in an external entity such as director, officer, partner, trustee, agent, or any position of management.
- **Intellectual Property Rights (IP)** (*e.g.*, patents, copyrights, or trademarks) upon receipt of ANY income related to such rights or interests.

**Investigator<sup>11</sup>:** "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."

**Institutional Conflict of Interest (ICOI):** An Institutional Conflict of Interest exists when the COI Committee determines that Albert Einstein College of Medicine and Montefiore Medical Center have an institutional financial interest related to research conducted under its purview.

**Institutional Financial Interests:** Institutional Financial Interests means the following financial or business interests of Einstein and Montefiore:

- Einstein and Montefiore have the potential to receive milestone payments and/or royalties from the commercialization of a product based at least in part on technology that is the subject of the research.
- Einstein and Montefiore have equity in a company (publicly or non-publicly traded) involved in the research.
- Significant gifts or donations have been made to Einstein and Montefiore from an entity involved in the research.
- Senior leadership who may be able to influence the research's conduct have a related SFI.

**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.

- **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.

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<sup>11</sup> 76 Fed. Reg. 53284 (Aug. 25, 2011)

**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.

**Senior/key personnel:** Any person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution.

**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.

**Significant Financial Interest:** 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 (e.g., a financial interest in the sponsor of the research or the product or service being tested):

- 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, or trademarks), 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 education<sup>12</sup>, or income from service on advisory committees or review panels for a federal, state, or local government agency, or an Institution of higher education.

**Effective Date**

Effective as of: 28 March 2018

Revised as of: 11 April 2024

**Policy Management and Responsibilities**

Einstein's Office of Human Research Affairs is the Responsible Office under this Policy. Einstein's Interim Senior Associate Dean for Clinical and Translational is the Responsible Executive and Einstein's Executive Director of the OHRA is the Responsible Officer for the management of this policy.

**Approved (or Revised)**

DocuSigned by:  5E34FE6DE4D2433...	04/19/2024
Responsible Executive	Date

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<sup>12</sup> As defined in 20 U.S.C. § 1001(a)