

# Guidelines for Conflict of Interest Disclosure

## I. Purpose

To ensure compliance with the Albert Einstein College of Medicine (Einstein) Conflict of Interest Policy, all potential conflicts of interest must be disclosed. This document explains that procedure.

## II. Scope

This procedure 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).

## III. Procedure

### A. 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 IV 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 updated 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's 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 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.

## **B. 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.

## **C. Disclosure of Travel<sup>1</sup>**

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.

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<sup>1</sup> Federal Register, 76, August 25, 2011 pg. 53284

- 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.

#### D. 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.

#### E. References

##### **Conflict of Interest Policy**

See the document entitled COI-POL-2018-002 Einstein Comprehensive Conflict of Interest Policy for additional information.

##### **Conflict of Interest Disclosure Form**

Access available at <https://einstein.coiriskmanager.com>. Access requires a MMC AD username and password. Please contact [COI@einsteinmed.edu](mailto:COI@einsteinmed.edu) for instructions on how to acquire your MMC AD. Replies from the COI e-mail account occur during business hours only.

#### **IV. Definitions**

**Institutional Responsibility:** Institutional responsibilities include research, teaching, clinical practice, and institutional administration. Any SFI or relationships with external entities related to these responsibilities must be disclosed.

**Roles Requiring Disclosure:** A leadership, consultative, decision-making, or other fiduciary role in a corporate entity of organization external to Einstein.

##### **Significant Financial Interest (SFI): as per federal definitions**

- With regard to a publicly traded entity, SFI exists if the value of any remuneration (salary or payment for services) from the entity in the twelve months preceding disclosure, and the value of any ownership interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.
- With regard to a non-publicly traded entity, SFI exists if the value of any remuneration (salary or payment for services) in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator or related party holds ANY equity interest.

- Intellectual property (IP) rights and interests (e.g., patents, copyrights) Disclosure must be updated within 30 days if any new remuneration from or ownership interest in an entity results in an aggregated value of \$5,000 or more.

## **V. Effective Date**

Effective as of: 28 March 2018

## **VI. Procedure Management and Responsibilities**

Einstein's Conflict of Interest Office is the Responsible Office under this procedure. 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 procedure.