

Disclosing Financial Conflicts of Interest to the Einstein IRB

I. Purpose

This Procedure describe the process for the review of investigator financial conflicts of interest by the Einstein Institutional Review Board (“IRB”).

II. Scope

This Procedure applies to all investigators and key personnel affiliated with Albert Einstein College of Medicine (“Einstein”) or Montefiore Medical Center (“MMC”) conducting research under the auspices of the Einstein IRB.

III. Definitions

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

Financial Interest (FI): FI exists if the investigator or key personnel 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.

Significant Financial Interest (SFI): Any financial interest consisting of one or more of the following, that reasonably appears to be related to the investigator or key personnel’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 investigator or key personnel 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, or income from service on advisory committees or review panels for a federal, state, or local government agency, or an institution of higher education.

Institutional Responsibilities: Any research, teaching, or administrative functions on behalf of Einstein.

IV. Procedure

A. Disclosure to the IRB

Investigators and key personnel are required to disclose significant financial interests to the Conflict of Interest Office in accordance with Einstein's "Comprehensive Conflict of Interest Policy." In addition, investigators are responsible for complying with MMC's general Conflicts of Interest policy (Administrative Policy and Procedure No. JH20.1), as applicable.

Investigators should consult their department chairs to determine if the department has a significant financial interest related to the research and should disclose any such information.

Investigators must disclose recruitment bonuses paid per participant or for reaching an accrual goal within a specific time frame, as well as being offered a finder's fee for referral of potential participants.

N.B. Payments to physicians for referring patients to research protocols in which the referring physician does not participate as an investigator are prohibited.

During the course of the research, information pertaining to new or changed financial interests must be disclosed in a timely manner.

B. IRB Review of FCOI Management Plan

Review of a protocol by the IRB is contingent upon submission of required conflicts of interest disclosure(s) to the Conflict of Interest Office.

The Conflict of Interest Office determines whether the disclosed interest represents a financial conflict of interest with respect to the protocol and proposes a management plan if necessary. The Conflict of Interest Office will inform the IRB of such management plan.

The IRB will review the FCOI management plan to determine if the specific mechanisms proposed to mitigate the conflict are adequate to protect potential research subjects. The IRB has the final authority to decide whether the interest and its management, if any, allows the research to be approved.

V. Effective Date

Effective as of: July 1, 2020

VI. Procedure Management and Responsibilities

Einstein's Office of Human Research Affairs is the Responsible Office under this Procedure. The Executive Dean is the Responsible Executive for this Procedure. The OHRA Director is the Responsible Officer for the management of this Procedure.