# Policy on Disclosing Financial Conflicts of Interest to the IRB

## I. Ethical Context and Principles

A. Research involving human subjects is ethically justified by the continuing need to search for knowledge, to enhance scientific understanding, and to improve patient care.

B. Three ethical principles underlie human subjects research:
   1. Respect for persons
   2. Beneficence
   3. Justice.

   The first two require that there be open and honest sharing of information so potential subjects may make informed choices about participating or not participating in research.

C. Potential conflicts of interest related to human subjects research are inherent in that academic advancement and professional reputation are dependent on recognition through publishing and presentation of research results. When financial gain is also possible, an additional dimension for potential conflict emerges.

D. Patients, who may be concerned about conflicts of interest related to managed medical care, may also be concerned about potential conflicts of interest if recruited to participate as subjects in research.

E. Research subjects are asked to trust that the researcher has considered their interests in suggesting entrance into a protocol; that risks have been minimized; and that the intervention or experimental course of treatment will be monitored carefully. This trust is violated if self-interest (conflict of interest) interferes with the professional judgments of the researcher.

F. The doctrine of informed consent requires that a potential research subject consider the risks, benefits, and alternatives to the proposed research intervention. They must be given all the information that would be reasonably relevant to their choice, including information about potential conflict of interest.

G. Disclosure of significant potential conflicts of interest is essential to the integrity and ethical propriety of the informed consent process and to maintaining public trust in and support for the research endeavor.

## II. Definitions[1]

A. ***Financial interest*** means anything of monetary value, whether or not the value is readily ascertainable

B. ***Significant financial interest*** means a financial interest consisting of one or more of the following interests of the Principal Investigator or any Key Person (and those of the PI's or Key Person's spouse and dependent children) that reasonably appears to be related to their institutional responsibilities:
   1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, and/or the value of any equity interest in the entity as of the date of disclosure, when aggregated,

[1] Einstein employs definitions as promulgated by DHHS (Fed. Reg. 76:53256ff 8/25/2011

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.

2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds **any** equity interest (e.g., stock, stock option, or other ownership interest).
3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
4. Disclosure must include any reimbursed or sponsored travel (i.e., that which is paid on behalf of the PI or Key Person (and not reimbursed so that the exact monetary value may not be readily available) related to their institutional responsibilities (this disclosure requirement does not apply to travel that is reimbursed or sponsored by a 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)*.*
5. The term **Significant Financial Interest** does not include the following: salary, royalties, or other remuneration paid by an institution to a PI or Key Person if they are currently employed or otherwise appointed by that Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements or from service on advisory committees or review panels on behalf of a 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.

C. ***Financial conflict of interest*** **(FCOI)** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

D. ***Institutional Responsibilities*** means any research, teaching, or administrative functions on behalf of Einstein.

## III. Disclosure[2]

A. As part of the submission of a human subjects research protocol to the IRB, investigators and other Key Personnel must disclose **any** interest consistent with the definition of a **Significant Financial Interest**, as set forth above. The disclosure must describe the nature of that interest and its relationship to the proposed protocol. It is the responsibility of the institution to determine whether the disclosed interest represents a **Financial Conflict of Interest** with respect to

[2] See conflict of interest disclosure form attached.

the protocol (as defined above), and to propose mitigation. Review of a protocol by the IRB shall be contingent on submission of required conflicts of interest disclosure(s).

B. PIs should consult their Department Chairs to determine if the Department has a significant financial interest (as defined above) related to the research and should disclosure any such information.

C. PIs must also 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.

D. Investigators must also disclose financial interests as required by the funding or reviewing agency or other governmental agencies. In addition, investigators are responsible for complying with Einstein's Comprehensive Policy on Conflict of Interest, and/or Montefiore Medical Center's general Conflicts of Interest policy (Administrative Policy and Procedure No. JH20. 1), and/or with NYC Health and Hospitals Corporation policies, as applicable relative to their employment. Disclosure to the Einstein IRB does not relieve the individual of this responsibility.

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

## IV. Role of the IRB

A. The IRB must be composed of impartial members who are not under undue influence by institutional pressures to approve research in which an individual or the institution may have potential financial interest.

B. An IRB member with a significant financial interest pertinent to a specific study or its sponsor, as determined by the IRB, should not participate in the review of or determination concerning that study.

C. The IRB should be informed of the source(s) of funding and funding arrangements for each protocol. Specifically, the IRB might consider the answers to the following questions in its deliberations:

   1. Who is the sponsor?
   2. Who designed the clinical trial?
   3. Who will analyze the safety and efficacy data?
   4. Is there a Data Safety Monitoring Board (DSMB)?
   5. Are there any financial relationships between the PI and/or Key personas and a commercial sponsor?
   6. Is there any compensation that is affected by the study outcome?
   7. Does the Investigator (or spouse, dependent children) have any proprietary interests in the product, including patents, trademarks, copyrights, and licensing agreements?
   8. Does the Investigator (or spouse, dependent children) have equity interest in the company-- publicly held company or non-publicly held company?
   9. Does the Investigator receive significant payments of other sorts? (e.g. grants, compensation in the form of equipment, retainers for ongoing consultation, or honoraria)
   10. What are the specific arrangements for payment?
   11. Who receives the payment? The Institution? The Investigator?

12. Is payment amount based on the number of subjects enrolled? What is the payment per participant? Are there other arrangements?

D. When a financial interest has been disclosed, the IRB will refer the disclosure to the Committee on Conflict of Interest, which shall be responsible to review the matter as outlined in Einstein's Comprehensive Policy on Conflict of Interest.[3]

E. The Committee on COI shall determine whether a **Financial Conflict of Interest** exists, and shall propose specific mechanisms proposed to mitigate the conflict in order to protect the interests of potential research subjects. In general, if **Financial Conflicts of Interest** are identified, the involved person should not be directly engaged in aspects of the trial that could be influenced inappropriately by that conflict. These might include: design of the trial, monitoring the trial, obtaining the informed consent, adverse event reporting, and analyzing the data. In addition a determination shall be made whether the research protocol may be reviewed by the Einstein IRB, and/or whether the protocol may be permitted to be carried out under the aegis of Einstein, at Montefiore, and/or at the North Bronx Healthcare Network.

F. The IRB shall be responsible for implementing and monitoring the mitigation plan, In all cases, good judgment, openness of process, and reliance upon objective, third party oversight can effectively minimize the potential for harm to subjects and safeguard the integrity of the research.

## V. Disclosure to Potential Subjects

A. As part of the informed consent process, potential subjects should be informed about financial conflicts of interest in language that conveys the nature of the conflict and facilitates comprehension. Potential subjects do not necessarily need information about the size of the financial interest to make an informed decision about participating in research.

B. The language used to describe conflicts of interest to research participants should be designed to inform subjects without creating a barrier to research.

C. Disclosure should be provided in the section of the informed consent form, entitled "Conflicts of Interest," which should be drafted by the investigator and approved by the IRB.

1. For company sponsored research, this section may contain the following statement: "This research, as with most drug studies, is funded by the company that manufactures this new drug."
2. For financial conflicts of the PI or Key Persons, a statement such as the following may be appropriate: "An investigator on this study has a relationship with the company sponsoring the research as follows: [insert specifics]. "
3. The Committee on COI or the IRB may require more specific language

D. Conflicts of interest generally should be disclosed to subjects in the circumstances listed below. (Determination whether a **Financial Conflict of Interest** exists will be made on an individual basis for each protocol.)

1. The study is sponsored by the manufacturer of the drug or device under investigation;
2. The medical school/medical center holds a financial interest in the company and could benefit from the study findings or in the drug or device

[3] See Comprehensive COI Policy http://www.einstein.yu.edu/administration/conflict-of-interest/default.aspx?id=27490

under investigation. The Department Chairperson or study investigators have knowledge of such an interest;

3. The PI or other investigators or their family members (spouse or dependent children) have a significant financial interest in the company and could benefit from the study findings;
4. The PI’s or their spouses or minor children have a significant financial interest in the particular drug or device under investigation; and
5. The Principal Investigator's Department has a significant financial interest in the outcome of the research or in the company and could benefit from the study findings.