Policy on Disclosing Conflicts of Interest

I. INTRODUCTION

An important part of the scientific, academic and clinical efforts of the Albert Einstein College of Medicine of Yeshiva University (Einstein) is the discovery, development and application of new knowledge that will 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. Einstein supports these mutually beneficial collaborative efforts provided such efforts do not result in conflicts of interest. The Conflict of Interest Policy is also intended to maintain the professional autonomy of scientists and physicians inherent in the self-regulation of science. (See also Human Resources Policy No. 7.)

While the provisions of the Conflict of Interest Policy apply to individual faculty members, trainees, and key personnel of research teams (as that term is defined by NIH and CCI policies), the concept of responsibility inherent in this policy pertains to clinical and academic departments, members of Administration, as well as to Einstein faculty and staff as a whole. Thus, one essential element of the policy is to ensure that the integrity of all activities at Einstein will in no way be compromised by past, current, and anticipated relationships between the institution and any other enterprise.

It is necessary for those involved in research to structure their relationships with commercial and other outside activities and entities to conform with their responsibilities for teaching, research, and patient care, as well as their responsibilities to Einstein, the government, and the public. It is a major intent of this policy to alert faculty members to recognize and avoid situations that constitute conflicts of interest.

An integral part of the policy is the requirement that faculty members employed by Einstein, trainees, administrators, and key personnel of research teams, disclose for review by Einstein any activity or association that might constitute a conflict of interest. These activities include any outside business relationship that is both relevant to the individual's academic or employment activities and that may create a financial gain for that individual or his family. These same principles and objectives apply to faculty on the payroll of affiliates, whose employing institutions are responsible for assuring compliance when conducting programs that utilize any of Einstein's facilities. By virtue of the requirement for full disclosure and review of possible conflict of interest situations, this policy will provide assurance to the faculty, Einstein, and the public that such outside business relationships have been examined, and will be conducted in a manner consistent with institutional and public values and policies. 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.

II. JURISDICTION

The general principles and objectives of Einstein’s conflict of interest policy govern all programs conducted at Einstein, sponsored by Einstein or using the Einstein name, or utilizing any Einstein facilities. The Einstein reporting and disclosure requirements of this policy apply to all faculty, key research personnel, and trainees employed by Einstein and to voluntary faculty subject to this policy, as defined above. Those researchers who are employed by an Einstein affiliate should note that their employing institution retains responsibility for assuring compliance to the general principles set forth in this policy. Einstein will require the full cooperation of its affiliates in adopting and enforcing conflict of interest policies of their own, applicable to faculty in the employ of that affiliate that conform to the general principles and objectives and procedures established by Einstein. In those instances where the Dean has information that faculty in the employ of an Affiliate who are subject to this policy may not be adhering to the general principles and objectives of Einstein’s policy, the Dean shall commence action under this policy by presenting such information to the Committee on Conflict of Interest.

III. ETHICAL CONTEXT AND PRINCIPLES WITH REGARD TO RESEARCH

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

2. 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. There have always been conflicts of interest imbedded in research, as academic advancement and professional reputations were dependent upon the publishing of results in the research arena. When there is a possibility for financial gain, an additional potential source of conflict becomes evident.

3. Additional protections are required with research that involves human subjects. One must be sure that issues related to informed consent and possible disclosure are adequately addressed and that the self-interest of the researcher does not interfere with professional judgments.

IV. DEFINITIONS

Significant Financial Interest means anything of monetary value, including but not limited to salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:

* Salary, royalties, or other remuneration from the applicant institution;
V. COMMITTEE ON CONFLICT OF INTEREST

The Dean will appoint, in conformity with the academic procedures of Einstein, a standing committee known as the Committee on Conflict of Interest, which will be composed of a balanced representation of the clinical and pre-clinical faculties, as well as ex-officio representatives from the Administration of the College or University, as needed.

The Committee on Conflict of Interest will appoint a Screening Subcommittee to promptly review all cases of potential conflict of interest forwarded to it. Within 7 days of the receipt of a potential conflict of interest, the Screening Subcommittee will discuss the potential conflict of interest with the involved person and will make recommendations to the Conflict of Interest Committee as to whether an impermissible conflict of interest exists, together with a recommendation as to what monitoring or other actions are appropriate to remove or adequately mitigate the conflict of interest. The Committee on Conflict of Interest will provide the involved individual with a written explanation and justification of the basis for its recommendations. The Committee on Conflict of Interest will provide the person involved with the opportunity to respond either in person and/or in writing to the issues raised by the Screening Subcommittee. The involved person may request that the findings and recommendations of the Screening Subcommittee be reviewed by the entire Committee on Conflict of Interest.

Upon receipt of the decision of the Conflict of Interest Committee, the individual involved may, within thirty (30) days, submit new and relevant information that could effect the decision rendered, and may request reconsideration of the decision by the Committee. The Committee should 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.
The Committee on Conflict of Interest will report its findings to the Dean with copies, as appropriate, to the Director of Conflict of Interest, the Associate Dean for Academic Affairs, the Department Chairman, the Committee on Clinical Investigations, sponsors, and governmental agencies. If findings of a potential conflict of interest are related to human subject research, the Screening Subcommittee on Conflict of Interest should consult with legal counsel to see what steps, if any, are required to manage, reduce or eliminate, the conflict. When such findings are reported to the Committee on Clinical Investigations (CCI), the CCI is responsible for implementing the recommendations of the Committee on Conflict of Interest. (Should the CCI disagree with the recommendations, it may submit its findings and request reconsideration by the Committee on Conflict of Interest). The CCI shall refer the report of the Committee on Conflict of Interest to its Subcommittee on Conflict of Interest that shall meet to determine parameters for disclosure to subjects, protocol amendments, or such other modifications.

VI. REPORTING AND DISCLOSURE

All individuals subject to this policy are required to complete a Conflict of Interest Disclosure Form:

a. At time of initial appointment to Einstein;
b. Subsequent to initial appointment whenever circumstances arise that may either (a) constitute a new conflict of interest, or (b) change the facts applicable to a previously disclosed potential conflict. Such a report must be filed within 30 days;
c. Upon submission of human subject research protocols for review and approval by the Committee on Clinical Investigations; and
d. Periodically thereafter as determined from time to time by the College of Medicine

All individuals subject to this policy are also required to attest to no reportable conflict of interest (or to report a potential conflict of interest at such time), upon:

a. Submission of a human subject research protocol Progress Report for review and approval by the Committee on Clinical Investigations;
b. Submission of grant application to the Office of Grant Accounting;
c. Appointment as a member of the Committee on Clinical Investigations; and
d. Submission of a contract for industry-sponsored research.

If the potential conflict of interest relates to research activities, all involved individuals must report as follows:

1. Individuals must complete a Committee on Conflict of Interest Disclosure Form whenever they have an interest in any research or its sponsor that meets or exceeds the definition of a financial interest; and must describe the nature of that interest.
2. Individuals must also disclose financial interests as required by the funding or reviewing agency or other governmental agencies. This includes compliance with PHS and FDA requirements.

3. Investigators must also disclose recruitment bonuses paid for human subject research 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 research subjects.

4. Department Chairs should inform the Committee on Conflict of Interest if the Department or a faculty/staff member has a financial interest of which they are aware (as defined above) in the outcome of any departmental or institutional research.

5. Financial interests of the institution, known to Faculty/staff conducting or planning research, or known by the administrative member of the Committee must also be disclosed to the Committee on Conflict of Interest.

During the course of the research study, new information that falls within the reporting requirements of this policy must be disclosed to the Committee on Conflict of Interest in a timely manner.

All reports of potential conflicts of interest will be forwarded to the Chairman of the Screening Subcommittee, who is appointed by the Dean. The initial Chairman will be the Director of Conflict of Interest who will note such report and ascertain whether Einstein is institutionally aware of other information relevant to this report. All material will be forwarded to the Screening Subcommittee on Conflict of Interest, which will evaluate the data and submit its recommendations to the full Conflict of Interest Committee.

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.

6. For any interest that the Institution identifies as conflicting subsequent to the Institution’s initial report under the award, a report will be made 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.

7. 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.

8. The Conflict of Interest Committee will maintain records of all financial disclosures and all actions taken by the Institution with respect to each 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.

VII. ROLE OF THE COMMITTEE ON CLINICAL INVESTIGATIONS (CCI)

1. A CCI member with a conflict of interest associated with a specific study, investigator, or its sponsor, shall not participate in review and approval of that study, except to provide information as requested by the CCI.

2. The CCI shall be cognizant of the source of funding and funding arrangement for each protocol.

3. When a potential conflict of interest not previously disclosed is identified by the CCI, the CCI shall request that the Investigator complete a Conflict of Interest Disclosure Form for submission to the Committee on Conflict of Interest Screening Subcommittee. At such time, a review of the institution's or investigator's financial relationship to the Sponsor of a specific trial should be promptly conducted to determine whether the trial should be permitted to be carried out at Einstein, and under what guidelines. Until the propriety of the financial relationship is reviewed, the investigator shall abide by directives of the CCI concerning continuation of the research protocol.

4. The CCI shall carefully consider the specific mechanisms, guidelines, or restrictions proposed by the Committee on Conflict of Interest to minimize the potential adverse consequences of the conflict in an effort to optimally protect the interests of the research subjects. In general, if there are any significant conflict of interest issues on the part of the Investigator, as determined by the Committee on Conflict of Interest, he or she should not be directly engaged in aspects of the trial that could be influenced inappropriately by that conflict. These could include: the design of the trial, monitoring the trial, obtaining the informed consent, adverse event reporting, and analyzing the data. 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. All efforts should be made to insure that the research project is carried out within the framework of this policy.

5. As part of the informed consent process, potential human research subjects must, when required by the CCI, be informed about financial conflicts of interest in language that conveys the nature of the conflict and facilitates comprehension. In general, financial interests that could affect, or be perceived as affecting, the conduct of human research should be disclosed to potential subjects.
6. The language used to describe conflicts of interest to research participants should be designed to inform subjects without creating a barrier to research.

7. Disclosure should be provided under a newly created section of the informed consent form, entitled "Conflict of Interest," which will be drafted and approved by the CCI.

8. Financial conflicts of interest should be disclosed to subjects, as determined by the CCI, in the circumstances listed below. (The threshold in determining whether a financial interest exists of sufficient magnitude to warrant disclosure will be determined by the CCI and the Committee on Conflict of Interest on an individual basis for each protocol.)

9. The CCI or the Committee on Conflict of Interest may require that one or more of the following be disclosed to subjects:

   a. The study is sponsored by the manufacturer of the drug or device under investigation;
   b. The medical school/medical center holds a financial interest in the drug or device company and could benefit from the study findings or in the drug or device under investigation.
   c. Investigators or their family members (spouse or dependent children) have a significant financial interest in the drug or device company and could benefit from the study findings;
   d. The investigator’s or their spouses or minor children have a significant financial interest in the particular drug or device under investigation; and

VIII. SANCTIONS FOR NON-COMPLIANCE

The College of Medicine expects all individual faculty members, trainees, and key personnel of research teams 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 faculty member to possible sanctions. In such instances where the continuance of the individual in his duties threatens immediate harm to himself or others, or may cause irreparable damage to the College of Medicine, 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 of Yeshiva University. The Committee on Conflict of Interest 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:
(1) 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;
(2) 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 supervise students;
(3) notice to appropriate parties (including government agencies or otherwise) of the conflict of interest activity found to exist;
(4) dismissal from the College of Medicine.

**IX. NON-RETAIATION**

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.

**Conflict of Interest Form**

The Conflict of Interest Form is in PDF format. PDF forms require ADOBE ACROBAT READER. If you do not have it loaded or need to upgrade to the latest version, just click and download it now. It's very quick and easy.