



New England School of Acupuncture

Institutional Review Board

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Conflict of Interest Policy

The NESAS IRB has implemented a Conflict of Interest Policy and Procedures. The choice of full disclosure in place of categorical prohibitions is based on the assumption that once a conflict is recognized, it can be avoided or managed, reduced, or eliminated.

The policy is based on the following principles:

- Recognition that not all conflicting interests are necessarily impermissible.
- Reliance on complete, timely disclosure.
- Case by case assessment and analysis.
- Assurance of confidentiality (save for disclosure to superiors within a structure of accountability and to federal funding agencies when required under terms of the grant, contract, or cooperative agreement).
- A minimum of annual review and analysis of conflicts and/or potential conflicts.

In general, conflicts of interest relate to the potential for self-gain usually, but not always, of a financial nature. Potential for self-gain might serve to undermine the judgment or objectivity of investigators such that their primary mission and dedication to scientific values and to the protection of human subjects are compromised. Furthermore, not only bias, but the appearance of bias in research, may undermine public trust in the Institution.

The opportunity for investigators or scholars to receive financial or other personal rewards from their endeavors is not intrinsically unacceptable, as long as it does not adversely affect the objectivity, integrity, or professional commitment of an investigator. Investigators includes all individuals who are responsible for the design, conduct, and reporting of research.

A potential or actual conflict of interest exists when commitments and/or obligations to the Institution, to human subjects or to widely recognized professional norms are likely to be compromised by a person's other interests or commitments, especially economic, particularly if those interests or commitments are not disclosed. Federal Regulations provide that a conflict of interest exists if the reviewer(s) of disclosures determine(s) that a significant financial interest could "directly and significantly affect the design, conduct, or reporting" of federally funded activities.

<http://www.fda.gov/oc/guidance/financialdis.html>

This Policy applies to "significant financial or other interests" defined as:

Salary or other payments for services if equal to or greater than \$10,000/year for the employee and/or his/her immediate family members; equity interests (e.g., stocks, stock options or other ownership interests) equal to or greater than \$10,000 and/or 5% of a business entity held by the employee and/or her/his family members; intellectual property rights (e.g., patents, copyrights and royalties from such rights); holding of a position as an officer, director, agent, or employee of a business entity by the

employee and her/his immediate family members. Dependents, the spouse, and all members of the household are considered members of the immediate family.

Circumstances or relationships that must be disclosed or managed, reduced, or eliminated as to an investigator usually must also be disclosed or managed, reduced, or eliminated if the investigator knew or should have known that a member of his or her immediate family had such a relationship.

This Policy requires disclosure of information in the following situations:

Submission of a protocol to the Institutional Review Board

When/if a potential for conflict arises after the original submission any of the above activities

This Policy prohibits the following activities:

Academic freedom restrictions such as prohibitions on publication by subordinates;

Payments, gifts, incentives directly or indirectly to individuals conducting human subjects research, other than through the research account for that project;

The following examples illustrate potential or actual conflicts of interest:

- A. Accepting gratuities or special favors related to research, or administrative duties.
- B. Giving well paid lectures for entities whose economic or political interests are affected by an investigator's scholarly work.
- C. Undertaking evaluative research when the investigator or the investigator's immediate family members have a financial, managerial, or ownership interest in the sponsoring entity or in the entity producing the product to be tested.
- D. Entering into a paid consultant arrangement with an organization or individual having an economic interest in related research.
- E. Using students or employees of NESAs to perform services for a company in which an investigator has an ownership or other financial interest.
- F. Accepting support for research under terms and conditions that results be held confidential, unpublished, or significantly delayed in publication.
- G. Providing privileged access to information, developed and/or supported by NESAs or independent sponsors, to an entity in which the investigator has financial or other interests.
- H. Purchasing equipment, instruments, or supplies for research from a firm in which the investigator has a financial or other interest.
- I. Influencing the negotiation of contracts between NESAs and outside organizations with which an investigator has a financial interest or other relationship.

The above examples are not intended to be an exhaustive list, but they represent examples of potential conflicts of interest that must be disclosed, reduced, eliminated or otherwise managed prior to the materializing of the conflict.

I. POLICY

A. Investigators are required to make regular, timely, and full confidential disclosures to the NESAs IRB, using the disclosure form(s) included with this policy. This will generally include disclosure of all outside remunerative activities related to their research or administrative responsibilities. They must also disclose equities and positions of members of their immediate family which could create a conflict or the perception of a conflict of interest between their academic/scientific obligations and their outside interests.

B. The Conflict of Interest Policy also imposes the obligation on department chairs, and other supervisory administrators not to encourage or condone impermissible conflicts on the part of their investigators.

C. Sanctions may be applied for non-compliance with the requirements or provisions of this policy in the same way as for non-compliance with any other NESAs IRB policy, including removal from the particular project, letter of reprimand, and special monitoring of future work.

D. In order to encourage full disclosure of potential conflicts without unduly intruding on the privacy of NESAs personnel or their families, disclosures shall be treated confidentially and disclosed only to the extent necessary for review, to consider and manage, reduce, or eliminate any conflicts, and to comply with requests from federal funding agencies made in accordance with the terms of the grant, contract, or cooperative agreement.

E. Financial, personal, or professional relationships that raise a potential conflict of interest or its perception shall be fully and accurately disclosed in all formal communications relating to the sponsored research, including those in professional journals.

F. Investigators shall not exercise decision-making authority or exert influence concerning any NESAs relationship affecting an entity in which they or members of their immediate family have a personal or professional interest.

G. The free exchange of information is a fundamental value underlying the NESAs IRB mission. The NESAs community has the general right to know the nature, purposes, methods, results, and sponsorship of relevant research conducted within the Institution.

In order to avoid broad limitations on collegial communication, arrangements involving the receipt of confidential scientific information, which may not be shared with colleagues reasonably promptly, shall be kept to a minimum. Where such arrangements are unavoidable, the scope of the project shall be defined so as to permit the exchange of as much information as possible.

Insofar as possible all significant results of research shall be published or publicly disclosed with reasonable promptness whether the results are favorable or unfavorable to the interests of any sponsor. Certain restrictions or limited delays in dissemination of information may be warranted by scientific prudence, the need to prepare patent applications, other legal rights, or for other justifiable reasons.

H. NESAs Students and Employees shall not be exploited or their education compromised in the service of sponsored research or the financial gain of supervisors. Employment of students or fellows by companies in which investigators have economic interests must be disclosed by the investigator.

Investigators shall take all precautions necessary to ensure that students' progress and academic standing are not jeopardized by violations of any professional norms in projects in which they participate, or by students' unfamiliarity with the circumstances surrounding sponsored research.

I. Compensation arrangements for support of clinical studies shall not adversely affect the conduct or influence the outcome of clinical research.

II. PROCEDURES

A disclosure statement shall be made by investigators to the NESAs IRB with the submission of each new protocol. IRB review after disclosure must take place promptly and help investigators determine which interests are not in conflict, which conflicting interests may be permissible, and which conflicting interests place the investigator at risk of jeopardizing the integrity of his/her scientific work.

The enforcement of this policy on conflict of interest rests primarily with the NESAs IRB and/or the NESAs Institutional Official. In the event that a conflict of interest related to a federally funded project is identified after the project is underway, the IRB Chairman or the Institutional Official will report to the federal agency within 60 days that a conflict exists and action is being taken to manage, reduce, or eliminate the issue.

Some examples of appropriate actions to resolve conflicts of interest are:

- a. Public disclosure of significant financial interests in publications and presentations.
- b. Monitoring of research by independent reviewers.
- c. Modification of the research plan.
- d. Disqualification from participation in all or a portion of the funded research.
- e. Divestiture of significant financial interests.
- f. Severance of relationships that create actual or potential conflicts.

***Some of the language of this policy has been taken from the "Guidelines for Dealing with Faculty Conflicts of Commitment and Conflicts of Interest in Research" by the Association of American Medical Colleges, Copyright 1990, ACM Washington, DC.