



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 16 2004

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

TO: IC Directors
IC Deputy Directors
IC Scientific Directors
IC Clinical Directors
IC Extramural Directors
Deputy Ethics Counselors

FROM: Director, NIH

SUBJECT: Changes in the NIH Ethics Program

This is to inform you that effective January 12, 2004, the HHS Designated Agency Ethics Official (DAEO) appointed Raynard S. Kington to serve as the Deputy Ethics Counselor (DEC) for the NIH and the Office of the Director, NIH. DEC's are appointed by the DAEO and have primary responsibility for the administration of the ethics program at NIH.

As you all know, the NIH ethics program has been the recent subject of intense public, Congressional, and media scrutiny. I have already announced a number of responsive changes and initiatives aimed at strengthening the ethics program at NIH. In addition, I believe the centralization of certain ethics functions will also improve our program.

At present, the NIH Deputy Ethics Counselor serves as the DEC for the IC Directors and, with the concurrence of the OGC Ethics Division, the Deputy Ethics Counselors. After conferring with our DAEO, I have decided that effective immediately, Dr. Kington will also serve as the DEC for IC Deputy, Scientific, Clinical and Extramural Directors. In order to facilitate this change, please forward a copy of the most recent financial disclosure report from each of these individuals, along with a complete copy of all other ethics-related documents and records retained in relation to these individuals, to Holli Beckerman Jaffe, Building 2, Room BE06, within 30 days.

In addition, as envisioned in my November 20, 2003, memorandum, I have established the NIH Ethics Advisory Committee (NEAC), composed of members of the NIH community. I have attached a table of the initial membership of the committee. Effective immediately, this committee will review certain activity requests, and Dr. Kington will serve as the DEC in relation to activity requests within the jurisdiction of the NEAC. NEAC will review activity requests where an NIH employee will receive compensation from an outside entity, as follows:

1) NEAC will provide supervisory review and, if appropriate, approval for **all outside activity and award requests submitted by appointed or acting OD Senior Staff and IC Directors**. Consistent with the above-stated centralization of DEC authority, the NIH DEC will serve as the final arbiter of these requests.

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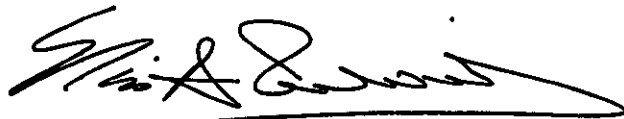
2) NEAC will advise the NIH DEC on **all outside activity and award requests submitted by IC Deputy Directors, Scientific Directors, Clinical Directors, and Extramural Directors.** The NIH DEC will serve as the final arbiter of these requests.

3) NEAC will advise the NIH DEC in relation to requests submitted by **any other NIH employee as follows:**

1. requests to accept awards from non-governmental sources that include a cash payment in excess of \$2,500;
2. any outside activity request involving a biotechnology or pharmaceutical company;
3. any outside activity request that involves anticipated compensation in excess of \$10,000, or which is expressed as a future income stream;
4. any outside activity for which payment will be, entirely or in part, in the form of stock, stock options, or other equity position.

Detailed instructions about the preparation and submission of these requests are attached. I realize that this represents a significant change in the administration of the NIH Ethics Program, but we must change to improve the oversight of our ethics program. After six months, I will review the new policy and make any necessary adjustments based on the experience of the NEAC. Dr. Kington has scheduled a meeting on January 26, 2004, to discuss this memo with DEC's and respond to any questions they might have.

We look forward to working with each of you, and want to take this opportunity to thank you for all of your ongoing and dedicated service.



Elias A. Zerhouni, M.D.

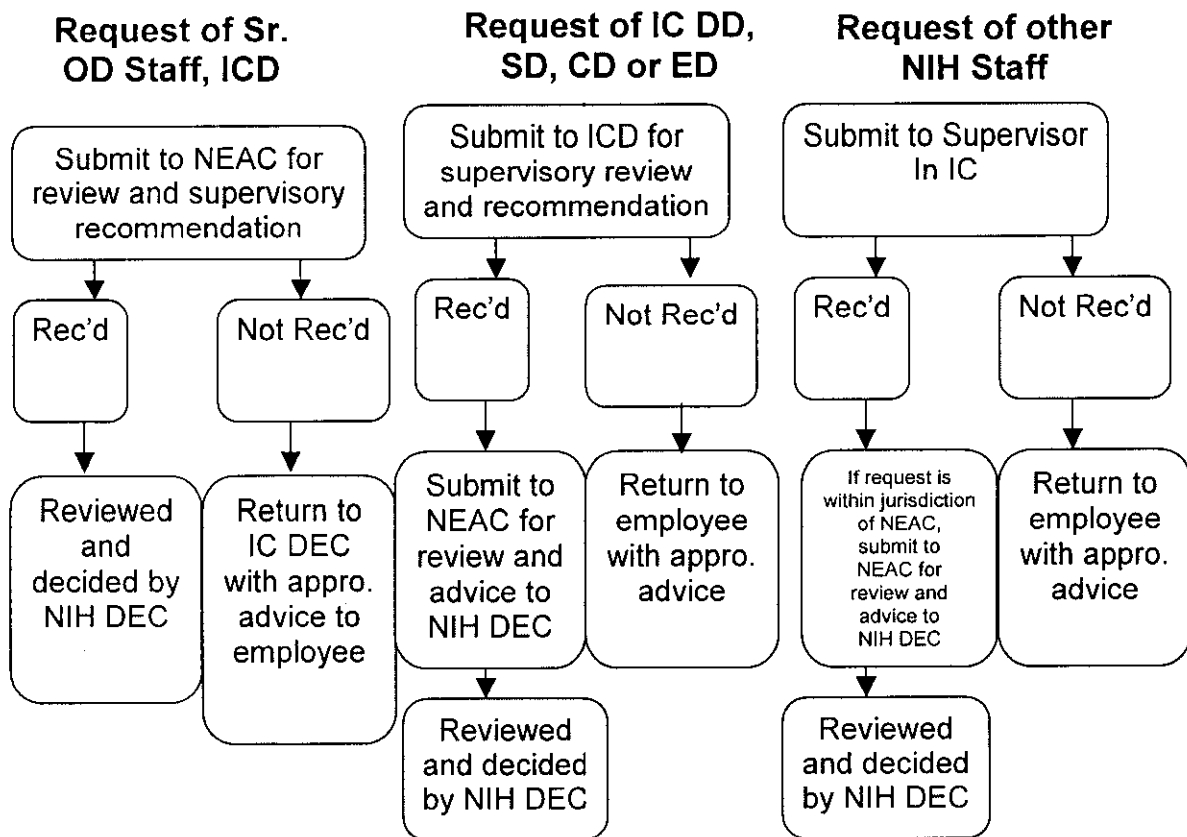
cc: Gretchen Weaver
OD Small Staff

Attachments

ACTIVITY REQUESTS SUBJECT TO NIH ETHICS ADVISORY COMMITTEE (NEAC) JURISDICTION

NEAC Jurisdiction: The NEAC will review all outside activity and cash award approval paperwork submitted by employees holding the following positions: IC Directors; IC Deputy Directors, Scientific Directors, Clinical Directors, and Extramural Directors; and OD Senior staff, including all NIH Deputy, Associate and OD Office Directors. Such paperwork submitted by other NIH staff will be reviewed by the EAC as follows: 1) cash awards where compensation exceeds \$2,500; 2) outside activities with biotechnology or pharmaceutical companies; 3) outside activities where total anticipated compensation exceeds \$10,000 or is expressed as future income stream; and 4) activities for which the compensation proposed is stock, stock options, or other equity position.

Procedure for submission: Employees and IC Ethics Program staff should prepare all required forms and paperwork and compile all appropriate additional information that the NEAC will need in order to complete its review. Once the paperwork and additional information is compiled, and the requesting employee has signed all forms, the IC DEC shall determine whether the request is subject to the jurisdiction of the NEAC and if so, proceed as follows:



NIH Ethics Advisory Committee
Membership January, 2004

Name	Category	Title	IC	Email	Telephone	Fax	Address
Dr. Duane Alexander	Senior Leadership	Director	NICHD	alexandd@mail.nih.gov	301-496-3454	301-402-1104	3172A03
Dr. Loré Anne McNicol	Staff Scientist (extramural)	Director, Division of Extramural Research	NEI	lam@nei.nih.gov	301-451-2020	301-402-0528	5635 Fishers Lane, MSC 9300, Suite 1300 Bethesda, MD 20892-7164
Dr. Harvey Klein	Staff Scientist (intramural)	Chief, Transfusion Medicine	CC	Hklein@cc.nih.gov	301-496-9702	301-402-1360	10/1C711
Dr. Nancy Nossal	Staff Scientist (intramural)	Chief, Laab of Molecular & Cellular Biology	NIDDK	ngn@helix.nih.gov	301-496-2724	301-402-0053	8/2A-19
Dr. Eric Green	Senior Leadership	Scientific Director	NHGRI	egreen@mail.nih.gov	301-594-8322	301-402-2040	50/5222
Dr. Cheryl Corsaro	Staff Scientist (extramural)	Scientific Review Administrator	CSR	corsaroc@csr.nih.gov	301-435-1045	301-480-2067	6701 Rockledge Drive, Room 2204, MSC 7890 Bethesda, MD 20892-7890
Dr. Joseph F. Fraumeni, Jr.	Senior Leadership	Director, Division of Cancer Epidemiology and Genetics	NCI	fraumenj@mail.nih.gov	301-496-1611	301-402-3256	EPS 8070 6120 Executive Boulevard, MSC 7242 Rockville, Maryland 20852-7242
Dr. Jeremy Berg	Senior Leadership	Director	NIGMS	bergl@nigms.nih.gov	301-594-2172	301-402-0156	45/2AN12
Dr. John La Montagne	Senior Leadership	Deputy Director	NIAID	jlamontagn@niaid.nih.gov	301-496-9677		3177A03
Dr. Faye Calhoun	Senior Leadership	Deputy Director	NIAAA	fcalhoun@mail.nih.gov	301-443-1269	301-443-7043	5635 Fishers Lane, Room 2003 Bethesda, MD 20892
Dr. Michael Gottesman	Co-Chair	NIH Deputy Director for Intramural Research	OD	Mgottesman@nih.gov	301-496-1921		1/103
Dr. Raynard Kington	Co-Chair	NIH Deputy Director	OD	KingtonR@od.nih.gov	301-496-7322	301-402-1150	1/126
Holli Beckerman Jaffe, J.D.	Ex officio		OD				
Gretchen Weaver, J.D.	Ex officio		OGC/OS				

The NIH Ethics Advisory Committee

Public service is a public trust. It requires employees to place loyalty to the United States Constitution, its laws, and ethic principles above private gain. At the National Institutes of Health, the first priority is to uphold the highest standards for patient safety, ethical practices, and scientific excellence. NIH has stringent standards and transparent policies for managing potential conflicts of interest.

The NIH Ethics Advisory Committee (NEAC) is one part of a multi-faceted system of ethics at NIH. This system is governed by the Standards of Ethical Conduct for Employees of the Executive Branch (Standards of Conduct), a government-wide system of ethics administered by the U.S. Office of Government Ethics, the Supplemental Standards of Conduct for employees of the Department of Health and Human Services, and by the directives of the Department of Health and Human Services Designated Agency Ethics Official.

Purpose

The purpose of the NEAC is to review and advise on proposed activities of NIH employees for which compensation will be received by the employee from an outside source. The NEAC is advisory to the NIH Deputy Ethics Counselor (DEC), who Co-Chairs the committee. With limited exception, the NIH DEC is responsible for providing final approval for the activities subject to the jurisdiction of the NEAC under all applicable rules.

Activities to be Reviewed

The NEAC will review certain proposed activities for which the employee will receive compensation from a non-governmental source. These include outside activities for compensation, such as consulting, advising, giving lectures, providing professional services, or writing or editing books. These also include lectures associated with cash awards and prizes given to an employee by an outside entity in recognition of the employee's government service. For senior NIH leadership, specifically, IC Directors; IC Deputy Directors, Scientific Directors, Clinical Directors, and Extramural Program Directors; and OD senior staff (including all NIH Deputy, Associate, and OD Office Directors), all such activities will be reviewed by the NEAC, and the NEAC will provide a supervisory recommendation.

In addition, a subset of the activities defined above will be reviewed by the NEAC regardless of the position of the employee proposing the activity: 1) cash awards where compensation exceeds \$2,500; 2) outside activities with biotechnology or pharmaceutical companies; 3) outside activities where total compensation is anticipated to exceed \$10,000 or is expressed as a future income stream; and 4) activities for which the compensation proposed is stock, stock options, or other equity position. The NEAC will advise the NIH DEC in relation to these requests and submissions.

Committee Membership

The NEAC will be Co-Chaired by the NIH DEC and Deputy Director for Intramural Research and consist of ten other rotating members and two ex-officio members (the NIH OD Ethics Officer and a representative of the OGC Ethics Division.) The rotating members will be appointed by the Co-Chairs and will be representative of the categories of employees submitting proposed activities to the NEAC for review, including IC Directors and Deputy Directors, Scientific Directors, Clinical Directors, certain Extramural Directors, OD Senior staff, and others. Because the DEC will make the ultimate decision, the DEC will be a non-voting member of the NEAC.

Scope of Review

NIH has a two-pronged system of review and approval for every proposed activity for which the employee will receive compensation from a non-governmental source. The first prong is review and approval of the activity by the appropriate supervisory authority, to ensure that the proposed activity will not interfere with the employee's official responsibilities.

The second is the ethics review and approval, to ensure that the activity does not violate the Standards of Conduct, the Supplemental Standards, or any Departmental directive, and is otherwise consistent with the government-wide system of ethics. Authority for this approval lies with the applicable DEC. The NEAC is expected to review proposed activities and advise the NIH DEC on the decisions to be made. For employees and activities within the scope of the NEAC review, the applicable DEC is the NIH DEC. The NEAC review does not supplant the current review and approval process for other activities governed by the Standards of Conduct, the Supplemental Standards, or other agency directive.

Specifically, Committee members will review each proposed activity and advise on whether the activity:

- 1) Conflicts with the employee's official duties;
- 2) Uses the employee's government position for private gain (or the private gain of someone with whom the employee has a covered relationship);
- 3) Influences the employee in the performance of an official act;
- 4) Induces the employee to take or omit an action in violation of the employee's official duties;

- 5) Creates an appearance of any of the circumstances outlined above; or,
- 6) Creates an appearance that any other ethical standard has been violated.

Terms used in this guidance shall have the meaning provided by the Standards of Conduct and shall be interpreted consistent with all applicable standards of conduct. Employees submitting proposed activities for NEAC review shall provide all pertinent information necessary for the Committee's review, such as the nature and extent of their official duties, identification of affiliated parties and covered relationships, most recent financial disclosure form, and other relevant information.

Review Criteria

The NEAC will review proposed activities under the following criteria.

1. Does the proposed activity conflict with the employee's official duties?

An activity conflicts with an employee's official duties if the activity is prohibited by statute or agency supplemental regulation or if it would require the employee's disqualification from matters so central or critical to the performance of the employee's official duties that his or her ability to perform the duties of the position would be materially impaired. The NEAC members should advise on whether recusals that would be required as a condition for approval of the proposed activity would materially impair the employee's ability to perform official duties.

2. Does the proposed activity use the employee's government position for private gain?

Employees are prohibited by law from using public office for his or her own gain, for the endorsement of any product, service, or enterprise, or for the private gain of others with whom the employee is affiliated. Private gain may arise through the inducement or coercion of benefits, if the employee uses or permits others to use his or her government position, title, or authority in a manner intended to coerce or induce another to provide a private benefit. It may arise through the appearance of governmental sanction, if the employee uses or permits others to use his or her government position, title, or authority in a manner that could reasonably be construed to imply that the government sanctions or endorses certain personal activities. Private gain may also arise through improper endorsements of private products, services, or enterprises, or where an employee's duties might affect the financial interests of persons with whom the employee has a covered relationship. These examples are not exhaustive.

The NEAC members should consider whether the proposed activity raises private gain or endorsement issues in light of the employee's official position and duties as well as in light of the employee's other outside affiliations and relationships.

3. Does the proposed activity influence the employee in the performance of an official act or induce the employee to take or omit an action in violation of the employee's official duties?

Employees must be impartial in the performance of their official duties. The NEAC should consider whether a proposed activity would cause a reasonable person with knowledge of the relevant facts to question the impartiality of the employee in carrying out official duties due to the nature of the particular matter, the particular parties, and the nature of the employee's official duties. The NEAC should also consider whether a proposed activity is likely to induce the employee to take or omit an action in violation of the employee's official duties.

4. Does the proposed activity use nonpublic information?

An employee is prohibited from engaging in a financial transaction using non-public information, as well as from allowing the improper use of nonpublic information to further his or her own private interest or that of another, whether through advice or recommendation or by knowing unauthorized disclosures. The NEAC members should advise on whether the proposed activity would be likely to involve the inappropriate use of non-public information.

5. Does the proposed activity involve the inappropriate use of government property?

Employees must protect and conserve government property and cannot use such property or allow others to use it for other than authorized purposes. Authorized purposes are those purposes for which government property is made available to members of the public or those purposes authorized in accordance with law, regulation, or NIH policy. The NEAC members should advise on whether the proposed activity would be likely to involve the inappropriate use of government property.