

MEMORANDUM

TO: OD Staff

FROM: Deputy Director, NIH and
Deputy Ethics Counselor, NIH

SUBJECT: Procedure for Review of Ongoing and New Outside Activities and Certain Awards

As you know, outside activities in which NIH employees engage and certain awards given to NIH employees have recently received significant media and Congressional attention. To assure that these activities in no way negatively affect our mission to advance the public health, we are reviewing all ongoing outside activities, and subjecting some activities and awards to heightened review by the newly established NIH Ethics Advisory Committee (NEAC). I write to explain the NEAC's jurisdiction and the procedures for submitting requests for approval of ongoing or new outside activities, and certain awards.

The NEAC has the following responsibilities and authority:

- 1) NEAC will provide supervisory review and, if appropriate, approval for **all outside activity and award requests submitted by appointed or acting NIH OD Senior Staff and IC Directors**. The NIH DEC will serve as the final arbiter of these requests.
- 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**:
 - requests to accept awards from non-governmental sources that include a cash payment, and/or travel reimbursement equal to or in excess of \$2,500;
 - any outside activity request involving a biotechnology or pharmaceutical company;
 - any outside activity request that involves total anticipated compensation in excess of \$10,000, or which is expressed as a future income stream;
 - any outside activity for which payment will be, entirely or in part, in the form of stock, stock options, or other equity position.

The attached documents entitled “NIH Ethics Advisory Committee,” and “Activity Requests Subject to the NIH Ethics Advisory Committee (NEAC) Jurisdiction” provide additional information.

As explained more fully below, you are required to provide specific information with respect to compensation if you wish to continue an outside activity or have a new activity considered for approval. Therefore, please comply with the following deadlines for review of ongoing and new outside activities:

- 1) For ongoing activities, submit packets through supervisory channels to the NIH Ethics Office (Bldg. 2/Room BE23/MSC0201) **no later than Tuesday, February 17, 2004**; and
- 2) For new outside activities, submit packets through supervisory channels to the NIH Ethics Office **at least six weeks in advance** of the anticipated start date of the activity.

If your activity is scheduled to occur prior to February 17, contact the NIH Ethics Office immediately for expedited review of the outside activity packet.

You should follow the already-established process for outside activity approval. That is, OD administrative staff is available to help you with preparing the packet and the NIH Ethics Office staff is available to advise on the appropriateness of any undertaking. Your supervisor must still approve the activity and the NIH Ethics Office must review it before the packet is forwarded to the NEAC. (If the activity does not fall within the NEAC’s jurisdiction, the activity will be reviewed and approved by your supervisor and me as the NIH DEC (through the NIH Ethics Office.) Once supervisory approval is obtained and the NIH Ethics Office review is completed, that will forward those activities that fall under the NEAC’s jurisdiction to the NEAC for action.

The following information must be submitted if you desire to have your request for approval considered or continued:

- **HHS Form 520.** This Form must now include information about the *amount* and *type* (e.g., cash, stock, or stock options) of income, compensation, fees, remuneration, expenses, or reimbursement that is to be received in connection with the ongoing or proposed activity. In addition, you must include, retrospectively, the cumulative amount of any income or other monetary receipts (including the type or method of payment) that was received by you from the outside source in connection with the ongoing activity for the past 5 years. We have been informed by the HHS Designated Agency Ethics Official that failure to provide the required information with respect to the amount and type of compensation will require me to cancel the ongoing outside activity or deny a request to begin a new one. The compensation information should be supplied in “Item Number 17” on the reverse of the HHS Form 520. Also, when reporting the period covered by the activity, the “from” date in box 8a of the Form 520 should reflect the date the activity originally started.

- **NIH Supplemental Information sheet to the HHS Form 520.** This supplemental sheet must include a thorough answer to question 3, “Explain how the proposed outside activity is different from the scientific activities performed as part of your official duties.”
- **NIH Form 2657.** This form must be completed by the employee and signed by the outside organization, where applicable.
- **Invitation Letter from Outside Organization.** Additional information that describes the activities and/or the organization may be included as well.
- **Your PD or Billet.** If you do not have a current PD or billet, please include a detailed explanation of your current job responsibilities.

Please note that any packet that is not complete will be returned, and approval will be held in abeyance until the packet is properly completed and the review can be performed.

If your request involves an already approved activity, you may reuse the previously submitted documents as long as all the required information is included, i.e., amend the previously submitted outside activity packets to include compensation information. You must, however, resign and redate the HHS Form 520.

If you have any questions, please contact the NIH Ethics Office at 301/402-6628.

Raynard S. Kington, M.D., Ph.D.

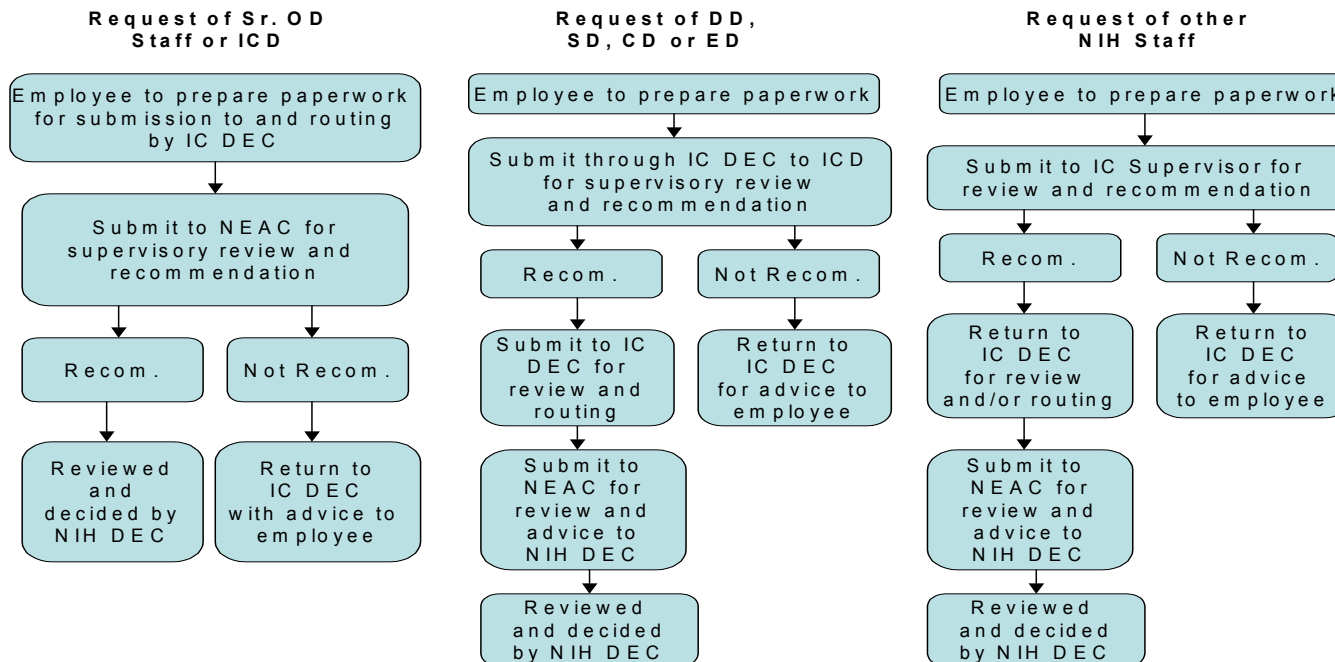
Attachments:

- Activity Requests Subject to NIH Ethics Advisory Committee (NEAC) Jurisdiction
- The NIH Ethics Advisory Committee

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

EAC Jurisdiction: The NEAC will review, without regard to compensation or dollar amounts, all outside activity and cash award approval paperwork submitted by employees holding the following positions: IC Directors, IC Deputy Directors, Scientific Directors, Clinical Directors, 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 NEAC as follows: 1) awards where compensation (inclusive of travel or other benefits) equals or 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 a future income stream; and 4) activities for which the compensation proposed is stock, stock options, or other equity position.

Procedure for submission: Employees, in consultation with their Program and IC Ethics 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 (and supervisor, where noted below) 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:



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 involving outside entities and/or 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) awards where compensation equals or exceeds \$2,500 (inclusive of travel and other benefits); 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.