NIH Policy Manual

2400-06 - NIH Ethics Advisory Committee (NEAC)

Issuing Office: OD/NEO **Phone:** (301) 402-6628

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Transmittal Notice

1. **Explanation of Material Transmitted:** This new chapter identifies the organization, structure, roles and responsibilities of the National Institutes of Health Ethics Advisory Committee (NEAC). The purpose of NEAC is to review and advise on certain proposed outside activities and awards bestowed upon NIH employees from outside entities. NEAC is advisory to the NIH Deputy Ethics Counselor (NIH DEC) or his/her designee. With limited exception, the NIH DEC is responsible for providing the final review and determination for the activities and awards subject to the jurisdiction of NEAC.

   Partial Revision: 12/23/2010*

   * 12/23/2010 revision incorporates the approvals specified in Section H. for years 2 and 3 of "*Presumed Approved*" activities and for Clinical Practice for New Employees.

2. **Filing Instructions:**
   Insert: NIH Manual Chapter 2400-06 dated 1/8/10.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.
- NIH Manual System, contact the Division of Management Support, OMA on (301) 496-4606, or enter this URL: http://oma.od.nih.gov/manualchapters

A. Purpose

Public service is a public trust. It requires employees to place loyalty to the United States Constitution and its laws and to the principles of ethical conduct above private gain. At the National Institutes of Health (NIH), the first priority is to uphold the highest standards for patient safety, ethical practices and scientific excellence. NIH has stringent standards and 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, governed by statutes, regulations, Presidential Executive Orders, directives from the Department of Health and Human Services (HHS) Designated Agency Ethics Official (DAEO), and NIH policies. The purpose of this manual chapter is to provide guidance to

employees regarding NEAC.

The purpose of NEAC is to review and advise on certain proposed outside activities of NIH employees and awards bestowed by outside entities. NEAC is advisory to the NIH Deputy Ethics Counselor (NIH DEC) or his/her designee. With limited exception, the NIH DEC is responsible for providing the final review and determination for outside activities and awards subject to the jurisdiction of NEAC.

The NIH Ethics Office (NEO) provides logistical and administrative support to NEAC, including but not limited to collecting, reviewing, and distributing submitted outside activity and award requests to NEAC members, and completing additional tasks to ensure outside activity and award requests are properly processed after NEAC review. In addition, the NIH Ethics Office maintains the official records of NEAC recommendations consistent with Section I. Records Retention and Disposal.

Terms used in this guidance shall have the meaning provided by the government-wide and HHS Supplemental Standards of Ethical Conduct and shall be interpreted consistent with all applicable standards of conduct. See NIH Manual Chapter 2400-01 Introduction to Government Ethics at the NIH for full definitions.

B. Employee's Responsibilities

Employees submitting outside activity and award requests subject to NEAC review shall provide all pertinent information necessary for the Committee's review, such as the nature and extent of his/her official duties, identification of any relationship the employee or NIH has with entities involved in or affected by the proposed outside activity or award, and any other relevant information as outlined in the HHS Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services (5 CFR 5501.106(d)(4)), including any additional information requested in connection with NEAC review.

C. Membership of NEAC

NEAC is comprised of individuals who occupy the following positions:

1. Two Co-chairs: The NIH Deputy Ethics Counselor (NIH DEC) and the NIH Deputy Director for Intramural Research (DDIR), or their designees;
2. Up to twelve rotating members, appointed by the Co-chairs, who are representative of the categories of employees submitting outside activity and award requests to NEAC for review, including but not limited to Institute/Center (IC) Directors, Deputy Directors, Scientific Directors, Clinical Directors, Extramural Directors, Senior Investigators and OD staff and;
3. Two ex officio members: the NEO Senior Policy Officer (or his/her designee) and a representative from the HHS Office of the General Counsel Ethics Division (OGC/ED).

In addition, the following attend NEAC meetings:

a. NEO's NEAC Coordinator or his/her designee, and;

b. Three rotating members of the NIH ethics community as observers, to be selected by the NEO Senior Policy Officer or his/her designee.

D. Jurisdiction of NEAC

NEAC reviews and issues recommendations to the NIH DEC for the approval or disapproval of employee requests to engage in outside activities and to receive awards consistent with Sections D.1 and D.2. The jurisdiction of NEAC is based on multiple criteria including, but not limited to, the employee submitting the action is an NIH senior employee (as defined in Section D.1); the type of the proposed outside organization; the nature of the proposed outside activity or award requirements; the value of compensation expected from the proposed outside activity; or the value of gifts associated with an award.

1. **Senior NIH Employees: All Outside Activities and Awards:** NEAC reviews all outside activity requests of, and awards offered to, senior NIH employees when approval is required by the government-wide and HHS NIH-specific standards of ethical conduct, and provides a recommendation to the NIH DEC. Senior NIH employees are: Institute/Center (IC) Directors

    a. Institute/Center (IC) Directors
    b. IC Deputy Directors
    c. IC Scientific Directors
    d. IC Clinical Directors
    e. IC Extramural Program Officials who report directly to an IC Director
    f. NIH Deputy Directors
    g. OD employees who report directly to the NIH Director

2. **All Other NIH Employees: Specific Outside Activities and Awards:** NEAC will review and advise the NIH DEC on the outside activities and awards which meet any of the following criteria, regardless of the position of the employee requesting the approval.

    a. Awards from foreign governmental or domestic entities where the employee will accept gifts associated with the award, and the aggregate value of those gifts equals or exceeds $2,500. Note: If a recipient employee travels to an award presentation event in his/her official capacity under the sponsored travel mechanism, the value of items accepted by the agency under the sponsored travel mechanism is excluded from determining NEAC jurisdiction. Sponsored travel is a gift to the agency, not to the employee;
    b. Outside activities with biotechnology and pharmaceutical companies. Note: In cases where the identified employer is an intermediary or other entity engaged in the business of providing services to other persons or entities, such as a law firm, venture capitalist, or marketing research firm, the underlying client of the intermediary is considered to be the employer and must be disclosed to determine whether the activity falls within NEAC jurisdiction;

c. Outside activities where total compensation exceeds or is anticipated to exceed $10,000 (including past and anticipated earnings) or is expressed as a future income stream (such as royalties);
d. Outside activities for which all or any portion of the compensation proposed is stock, stock options or other equity positions;
e. Outside activities which involve consultation with law firms and/or the delivery of expert testimony in any administrative or court proceeding;
f. Outside activities or awards for which a waiver of, or exception to, applicable regulatory prohibitions is permitted and requested; and
g. NEAC may sometimes review outside activity requests or awards at the request of the IC.

E. Scope of Review

NIH has a two-pronged system of review and approval for outside activities and awards. The first prong is review and recommendation by the employee's supervisor to approve or disapprove the outside activity or award based on whether the proposed outside activity or award will interfere with the employee's ability to perform central and critical official responsibilities.

The second prong is the ethics review and recommendation of approval or disapproval based on whether the outside activity or award violates applicable statutes; the Standards of Ethical Conduct for Employees of the Executive Branch; the HHS Supplemental Standards of Ethical Conduct; or any HHS directive; or is otherwise inconsistent with the government-wide system of ethics. Authority to approve or deny approval lies with the applicable DEC. NEAC is expected to review proposed outside activities and awards and advise the NIH DEC on whether the outside activity or award may be approved. For employees and outside activities or awards within the scope of NEAC jurisdiction, the applicable DEC is the NIH DEC.

F. Classification of Items for NEAC Review

Outside activities submitted to NEAC for review are categorized as *"Presumed Approved"* or *"For Discussion."*

1. ***Presumed Approved*** **Activities:** Certain outside activities are viewed as posing less risk of creating a real or apparent conflict of interest. These include:

    a. Teaching a course or giving a single lecture within an established curriculum of an educational institution (elementary, secondary, or higher education);
    b. Writing for a peer reviewed journal or textbook, or other publication subjected to a substantially equivalent editorial review process;
    c. Editing for a peer reviewed journal or textbook or other publication subjected to a substantially equivalent editorial review process;
    d. Clinical practice of medicine, dentistry, pharmacy, nursing, veterinary and animal husbandry or similar healthcare-related professional practice that involves the

personal provision of care, treatment, or healthcare-related professional services;
e. Clerical, administrative or retail activities with a prohibited source such as filing, bookkeeping, maintenance or janitorial work;
f. Non-scientific professional services where licensing and/or certification is required such as law, realty, engineering, architecture, fitness and exercise provided the employee's official duties are in a completely different field, and;
g. Board service for organizations and family-run businesses that are not scientific or healthcare-related, such as community and social organizations or real estate investment companies.

2. ***For Discussion*** **Outside Activities and Awards:** All outside activities and awards that are less common and/or merit particular attention due to intricacies involving such requests are categorized *"For Discussion."* These include:

    a. All outside activity and award requests for IC Directors;
    b. All requests to engage in consultation with law firms and/or the delivery of expert witness testimony in administrative or court proceedings;
    c. All outside activity requests to engage in consulting activities;
    d. All outside activity requests to engage in speaking activities outside an established curriculum of an educational institution such as CME or Grand Rounds;
    e. All outside activity requests to engage in board service for scientific organizations and other for profit organizations, and;
    f. All awards meeting NEAC jurisdiction.

G. Review Criteria for Outside Activities

NEAC reviews each proposed outside activity that falls within its jurisdiction and advises on whether the outside activity conflicts with the employee's official duties; uses the employee's government position for private gain; influences the employee in the performance of an official act; induces the employee to take or omit an official action in violation of the employee's official duties; creates an appearance of any of the circumstances listed above; or creates an appearance that any other ethical standard has been violated. This is further defined using the following criteria:

1. **Does the proposed outside activity conflict with the employee's official duties?** An outside activity conflicts with an employee's official duties if the outside 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/her ability to perform the official duties of the position would be materially impaired.
2. **Does the proposed outside activity use the employee's government position for private gain?** Employees are prohibited by law from using or permitting others to use their public office for their own private gain; for the endorsement of any product, service, or enterprise; or for the private gain of others. Private gain may arise through

the inducement or coercion of benefits if the employee uses or permits others to use his/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 the improper endorsement 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.

NEAC members consider whether the proposed outside activity raises private gain or endorsement issues in light of the employee's official position and duties, also taking into consideration the employee's other outside affiliations and relationships.

3. **Would the proposed outside activity influence the employee in the performance of an official act, or induce the employee to take or omit an official action?** An employee must be impartial in the performance of his/her official duties. NEAC considers whether a proposed outside 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 specific parties; and the nature of the employee's official duties. NEAC also considers whether a proposed outside activity is likely to induce the employee to take or omit an action in the context of the employee–s official duties.
4. **Does the proposed outside activity use nonpublic information?** An employee is prohibited from disclosing non-public information in the course of an outside activity, as well as from allowing the improper use of non-public information to further his/her own private interest or that of another, whether through advice or recommendation or through the knowledge of unauthorized disclosures. NEAC members advise on whether the proposed outside activity would be likely to involve the inappropriate use of non-public information.
5. **Does the proposed outside activity involve the inappropriate use of government resources?** An employee must protect and conserve government resources and cannot use such resources or allow others to use them for other than authorized purposes. Authorized purposes are those purposes for which government resources are made available to members of the public or those purposes authorized in accordance with law, regulation, or NIH policy. NEAC members advise on whether the proposed outside activity would be likely to involve the inappropriate use of government resources.

H. Exceptions to NEAC Review Jurisdiction for Outside Activities

Presumed Approved Activities Previously Reviewed By NEAC. Ongoing outside activities are reviewed and approved for a one-year period unless a shorter duration has been stated in the request. Outside activities that extend beyond a one-year approval period must be resubmitted for renewal no later than 30 days prior to the expiration of the approval period.

An exception to NEAC jurisdiction allows an outside activity request to be renewed and approved by the IC DEC. The IC DEC may review and approve a request to renew an outside activity in each of the two years following the last NEAC recommendation provided the outside activity meets the criteria set forth below. After two years of IC review, a request to continue the outside activity re-enters NEAC jurisdiction for review and recommendation for approval or disapproval by the NIH DEC. If the NIH DEC approves the outside activity, it will again be eligible for 2 years of IC DEC approval. Outside activity requests reviewed by NEAC and approved by the NIH DEC within the 12 months immediately preceding the effective date of this policy are eligible for IC DEC review and approval under this exception.

This exception covers activities that meet the following criteria:

1. The activity is *Presumed Approved* as defined in F.
2. The activity was last reviewed by NEAC, provided the last NEAC review occurred not earlier than 12 months prior to this policy's effective date; and
3. All of the following conditions are met:

    a. There is a supervisory statement indicating that there is no substantial change in the employee's official responsibilities since NEAC's previous consideration of the outside activity; and
    b. There is an employee statement indicating that there is no substantial change in the scope of the outside activity, compensation levels (except for incremental increases or decreases due to market conditions), and time commitment; and
    c. The following required documentation is included in the outside activity renewal request:

        i. A completed form HHS-520, "Request for Approval of Outside Activity";
        ii. The employee's current position description;
        iii. Form NIH-2657, "Supplement to Form HHS-520 Request for Approval of Outside Activity", if applicable;
        iv. When appropriate for clinical fellows, Supplemental Attachment to HHS-520 "Request for Approval of Outside Activity" NIH Fellows Providing Patient Care (e.g. Moonlighting);
        v. A syllabus, outline, summary, synopsis, or similar description of the content and subject matter of the proposed teaching, speaking, writing, editing activity, if applicable;
        vi. Documentation, where relevant, that the employee is in compliance with restrictions on the use of his/her title and NIH affiliation. Note: Documenting that the employee has been advised does not satisfy this criteria; and
        vii. Other relevant information including the outside employment contract, agreement, or invitation letter. Note: The contract, agreement, or invitation letter to engage in the outside activity may be the initial document and not a newly issued one if the initial document stated that the activity was for a prescribed period of time, i.e., for an established term of office.

The following chart illustrates changes in signatory authorities for outside activities that fall under the exception to the NEAC jurisdiction:

Year	Request Type*	Review/ Signatory Authority
1	Initial Request**	NEAC/NIH DEC
2	Renewal	IC DEC
3	Renewal	IC DEC
4	Renewal	NEAC/NIH DEC
**** Activities must be "Presumed Approved" and meet designated criteria to meet the exception.*** ***** May take place within 12 months prior to the effective date of this policy, or anytime after the effective date.***		

Clinical Practice for New Employees. New NIH employees seeking to engage in clinical practice where total compensation exceeds or is anticipated to exceed $10,000 (including past and anticipated earnings) may submit a hard copy HHS-520 to be reviewed and approved by the IC DEC. This approval will be valid for 90 days to allow the employee sufficient time to complete another HHS-520 via NEES, and to be reviewed by NEAC and receive the NIH DEC's determination with respect to the activity.

I. Records Retention and Disposal

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of the National Archives and Records Administration (NARA) General Records Schedule 25, Ethics Program Records, Items 1 and 9 (all items that apply). All other non-related records should be retained and disposed of under the authority of the NIH Manual Chapter 1743, "Keeping and Destroying Records," Appendix 1, NIH Records Control Schedule.

NIH e-mail messages: NIH e-mail messages (messages, including attachments, that are created on the NIH computer systems or transmitted over the NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, the NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages.

E-mail messages must also be provided to the Congressional Oversight Committees, if requested, and are subject to the Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

J. Internal Controls

1. **Office Responsible for Reviewing Internal Controls Relative to this Chapter (Issuing Office):** Through this manual issuance, the NIH Ethics Office is responsible for ensuring that internal controls are implemented and working.
2. **Frequency of Review:** Ongoing, annual review.
3. **Method of Review:** The NEO will maintain oversight and ensure effective implementation and compliance with this policy by monitoring the final approval of outside activities and awards falling under NEAC jurisdiction and through the process of IC Ethics Program Reviews conducted by the NEO.
4. **Review reports are sent to:** The NIH Deputy Director, the NIH Deputy Ethics Counselor and the Deputy Director of Management. Issues of special concern will be brought to the immediate to the attention of the NIH Deputy Ethics Counselor.

K. Additional Information

NIH policy states that employees will submit Form HHS-520 “Request for Approval of Outside Activity” electronically, using the NIH Enterprise Ethics System (NEES). For additional information, contact your IC’s Deputy Ethics Counselor (http://ethics.od.nih.gov/decs.pdf) or Ethics Coordinator/Specialist (http://ethics.od.nih.gov/coord.pdf), or the NIH Ethics Office (301-402-6628). Also, see the NIH Ethics Program web site, specifically the pages addressing (Outside Activities (http://ethics.od.nih.gov/topics/outside.htm) and Awards From Outside Organizations (http://ethics.od.nih.gov/topics/awards-new.htm)).

See the introductory chapter NIH Manual Chapter 2400-01, Introduction to Government Ethics at the NIH for information regarding relevant Authorities and References (Section D).