NIH POLICY MANUAL

1810-1 Procedures for Avoiding Conflict of Interest for NIH Special Government Employee (SGE) Advisory Committee Members

Issuing Office: Office of Federal Advisory Committee Policy (OFACP) 301-496-2123 Release Date: 12/31/05

 Explanation of Material Transmitted: This chapter sets forth policy and procedures to avoid the occurrence of conflicts of interest or the appearance of such conflicts, among Special Government Employees (SGEs) and other Federal employees appointed as members of NIH advisory committees and subject to the Federal Advisory Committee Act.

2. Filing Instructions:

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- Content of this chapter, contact the issuing office listed above.
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A. Purpose: This chapter sets forth policy and procedures to avoid the occurrence of conflicts of interest or the appearance of such conflicts, among Special Government Employees (SGEs) appointed as members of NIH advisory committees subject to the Federal Advisory Committee Act. Since Federal employees may serve as regular appointed members or ex officio members of National Advisory Councils and Boards, Program Advisory Committees, and Boards of Scientific Counselors, reference to conflict of interest procedures relevant to these members are also noted in this issuance.

This issuance describes procedures to ensure: (1) the appropriate collection, review, and evaluation of financial disclosure report forms and supplemental disclosure forms for prospective and current SGE advisory committee members and Federal employees serving as ex officio or regular members on advisory committees; (2) standardized methods of review of financial disclosure reports among Institutes and Centers; (3) appropriate verification and update of the Confidential Financial Disclosure Report (<u>OGE Form 450</u>); (4) waivers and authorizations are executed, where appropriate; (5) appropriate collection, review, and evaluation of the Foreign Activities Questionnaire (<u>HHS Form 697</u>) for prospective and current SGE advisory committee members; (6) SGE advisory committee members receive annual ethics training; and (7) confidentiality of information from these forms is maintained.

See <u>Appendix 1</u> for definitions of terms contained in this policy.

B. Background: The Standards of Ethical Conduct for Employees of the Executive Branch, 5 CFR Part 2635, became effective February 3, 1993, for all government employees, including SGE advisory committee members. Federal employees and SGE advisory committee members are also subject to the rules governing financial disclosure found in the Ethics in Government Act of 1978, as amended by the Ethics Reform Act of 1989, and Executive Order 12674, as modified by Executive Order 12731, and 5 CFR Part 2634. Additionally, Federal employees and SGE advisory committee members must comply with restrictions imposed by the Emoluments Clause of the U. S. Constitution (Article I, section 9, Clause 8) and the Foreign Gifts and Decorations Act (5 U.S.C. § 7342).

<u>C. Policy:</u> NIH's policy is to avoid conflicts of interest, or the appearance of such conflicts, in the selection and use of SGEs and Federal employees serving as advisory committee members and in the operation of advisory committees; to maintain adequate records regarding financial and organizational interests of such committee members; and to safeguard the confidentiality of these records.

It is essential that the work of committees not be compromised by any significant conflict of interest. A conflict of interest, for this purpose, means any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization. A conflict of interest is more than individual bias. There must be an interest, usually financial, that could be directly affected by the work of the committee.

D. Coverage: This issuance covers SGEs who are serving as appointed members of NIH National Advisory Councils and Boards, Program Advisory Committees, and Boards of Scientific Counselors. SGEs, for this purpose, are appointed to perform temporary duties on an intermittent basis for a period not to exceed 130 days during any period of 365 days. This issuance also covers all Federal employees who are appointed as regular or ex officio members of these committees.

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Since members of initial/integrated scientific and technical peer review groups are not appointed as SGEs, they are **not** covered by this issuance.

E. References:

1. Executive Order 12674 (April 12, 1989), as modified by Executive Order 12731 (October 17, 1990), "<u>Principles of</u> <u>Ethical Conduct for Government Officers and Employees.</u>"

2. <u>18 U.S.C. § 208</u>.

3. 5 CFR Part 2635, "Standards of Ethical Conduct for Employees of the Executive Branch."

4. 5 CFR Part 2634, "Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture."

5. <u>Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services</u>, 5 CFR Parts 5501 and 5502.

6. <u>Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects</u>, 42 CFR Part 52h.

7. NIH Manual 1130: Delegations of Authority, <u>General Administration #9B</u>, "Grant Conflict of Interest Waivers for IC Directors and Advisory Committee Members" (appointed by the Director, NIH, or Secretary, DHHS).

8. NIH Manual 1805: "Use of Advisors in Program & Project Review and Management."

9. NIH Manual 2300-735-1: "Avoiding Conflicts of Interest."

10. NIH Manual 1743: "Keeping and Destroying Records", Introductory Note and Parts 1100-G-6 and 1100-G-8-b.

11. Memorandum from Associate General Counsel for Ethics, "Issuance of Foreign Activities Questionnaire," dated May 10, 2002.

12. Emoluments Clause of the U. S. Constitution (Article I, Section 9, Clause 8).

13. Foreign Gifts and Decorations Act, 5 U.S.C. § 7342.

F. Responsibilities:

1. Institute and Center (IC) Deputy Ethics Counselors (DECs)

a. Ensure the avoidance of conflicts of interest, or the appearance of such conflicts, in the appointment of SGE advisory committee members.

b. Coordinate and manage IC financial disclosure reporting systems. Provide advice to IC staff and SGEs regarding the application of conflict of interest guidelines and completion of financial disclosure report forms.

c. Oversee, within their respective ICs, the implementation of policies and procedures set forth in this issuance and in accordance with other applicable laws, regulations, and policies.

d. Review and certify OGE 450 forms and other required documentation, i.e., waivers/addendums and authorizations for SGE members. (See <u>Appendices 2 and 2a</u>)

Approval and signature authorities delegated to the DECs may not be redelegated. Waivers/ addenda are effective upon signature of the DEC.

e. Review <u>SF 278</u>, Public Financial Disclosure Report, and <u>OGE 450</u>, Confidential Financial Disclosure Report, filed by Federal employees appointed as regular or ex officio members of NIH advisory committees, for any potential conflict of interest due to committee responsibilities. Inform employees of financial interests which could create a potential conflict in relation to committee responsibilities. Provide copies of any recusals and waivers to IC Committee Management Officers upon request.

f. Review <u>HHS 697</u>, Foreign Activities Questionnaire, to ensure compliance of the Emoluments Clause. (See <u>Appendix 3</u>).

2. Ethics Counsel, NIH, Office of the General Counsel, Ethics Division (OGC/ED)

a. Functions as the NIH liaison to the Office of Government Ethics (OGE).

b. Provides advice and guidance on conflicts of interest, financial disclosure, and foreign activities issues. When appropriate, provides detailed guidance to CMOs on new and/or changing conflicts of interest policies and procedures.

c. Ensures that policies and procedures affecting confidential financial disclosure systems and foreign activities are in compliance with Departmental and government-wide policies and procedures, disseminates HHS policies and procedures, and OGC/ED, OGE, and Department of Justice interpretations of Government ethics requirements, and provides guidance to NIH DECs.

d. Reviews SF 278 financial disclosure forms filed by the Director, NIH, the Director, NCI, and other Institute Directors who serve as DECs and as regular or ex officio members of NIH advisory committees, for any potential conflict of interest due to committee responsibilities.

e. Reviews and transmits a copy of each signed waiver/addendum issued under the authority of 18 U.S.C. § 208 to the OGE (See <u>Appendices 4</u>, <u>4a</u>, and <u>4b</u>.)

3. Director, Office of Federal Advisory Committee Policy (OFACP), OD/NIH

a. Functions as the liaison between the Office of the Secretary; the Office of the General Counsel, Ethics Division; the Office of the General Counsel, Public Health Service Division; the Department Committee Management Office; and the Institutes and Centers of NIH concerning conflict of interest matters relating to NIH SGE advisory committee members.

b. Furnishes policy and guidance to NIH officials for collecting, reviewing, and handling conflict of interest information for NIH SGE advisory committee members.

c. Establishes necessary controls and procedures to ensure compliance with applicable laws, regulations and policies, and submission of required documents and reports.

d. Coordinates all NIH advisory committee activities designed to avoid the occurrence of conflicts of interest or the appearance of such conflicts, in the nomination and selection of SGE advisory committee members.

4. Executive Secretaries (Designated Federal Officials) of NIH Advisory Committees

a. Acquire a working knowledge of pertinent statutes, regulations, policies, and procedures regarding conflict of interest and financial disclosure. Attend training sessions periodically on evaluation of conflict of interest situations.

b. Together with IC CMO, ensure that SGEs are fully aware of conflict of interest and financial disclosure requirements and, where appropriate, resolve any conflicts before service.

c. Review all OGE 450 forms from prospective SGE advisory committee members prior to appointment, all Verification forms (see Appendices <u>5</u>, <u>5a</u>, and <u>5b</u>) and Recusal Lists (see Appendix <u>6</u>) for current SGE members prior to each meeting. Advise the IC Deputy Ethics Counselor of potential or apparent conflicts of interest by waiver/addendum, or in some cases, by authorization. (See <u>Appendix 7</u>)

d. Review HHS 697 forms (see Appendix <u>3</u>) from prospective SGE advisory committee members prior to appointment, and then once yearly during their term of service.

e. Review grant and cooperative agreement applications to be considered individually at a Council or Board meeting. Determine that no member has a real or apparent conflict of interest which would preclude that member's participation in committee discussions concerning program or project concept development or concept clearance. Report any such situations to IC Director or other appropriate official(s).

f. Ensure that all Conflict of Interest and Confidentiality Certification forms (Certification) of no conflict of interest, and confidentiality of information forms that members complete at the meeting, are made part of the official meeting files.

g. Ensure that the procedures used to avoid conflicts of interest during the meeting are consistent with this issuance and are noted in the minutes of the meeting.

5. IC Committee Management Officers (IC CMOs) (hereafter referred to as CMO.)

a. Ensure that prospective SGE advisory committee members receive letters of invitation stating that their appointment is contingent upon review and approval of their completed OGE 450 form (see <u>Appendix 2</u>) and HHS-697 form (see <u>Appendix 3</u>), and that they receive an Administrative Fact Sheet (see <u>Appendix 8</u>) which provides instructions for completing the form. Also ensure that prospective members receive appropriate personnel appointment forms, the <u>Standards of Ethical Conduct website</u>, and other specified ethics materials.

b. Review prospective SGE members' OGE 450 forms to ensure that forms are completed properly. Ensure that current members receive a blank Verification form (see <u>Appendix 5</u>) along with a copy of their OGE 450 form and most recent Recusal List (see <u>Appendix 6</u>), for updating their financial interests and covered relationships prior to each meeting. Perform initial conflict of interest review of completed forms. Ensure that advisory committee members meet reporting deadlines.

c. Prepare Recusal List, identifying section 208 financial interests and section 2635.502 covered relationships. (See Appendices <u>6</u> and <u>9</u>.)

d. Review prospective members' HHS-697 forms for foreign activities applicable to the Emoluments Clause of the U. S. Constitution. (See Section I.) Consult with the NIH Ethics Counsel when necessary.

e. Obtain signature of acknowledgment, prior to each meeting, from Federal employees who have filed an SF 278 form or OGE 450 form, that current recusals and waivers remain in effect and of their agreement to report any changes in financial interests that may affect matters before the committee. (See <u>Appendix 10</u>.)

f. Ensure that new ex officio committee members are informed of the Office of Government Ethics and NIH's requirement that they and their alternates provide a copy of appropriate financial disclosure forms before attending a committee meeting. (See <u>Appendix 11</u>.) If an ex officio member or their alternate does not comply in a timely manner, CMO alerts the committee's Executive Secretary to obtain at the meeting a one-time certification of no conflicts of interest. (See <u>Appendix 12</u>.)

g. Ensure that all SGEs receive required annual ethics training (see <u>Appendix 13</u>) and maintain documentation that training material was sent, or the website address for reviewing the electronic training material was provided, and/or that in-person training was held.

h. Alert the IC DEC, Executive Secretary, or other appropriate IC officials, of any potential conflict or appearance problems, and advise on the proper procedures to handle such conflicts.

i. In consultation with Executive Secretary, prepare waivers/addenda/ authorizations for SGE advisory committee members, when appropriate, and discuss remedies for conflict or appearance problems with IC DEC or employing agency ethics officials for Federal employee members.

j. Ensure confidentiality and security of OGE 450 and other verification forms, and any other information obtained or prepared in connection with the forms, in accordance with the applicable Privacy Act System of Records and NIH policy. (See <u>NIH Manual 1743</u>, "Keeping and Destroying Records," Introductory Note and Part 1100-G-6.)

k. Provide copies of all waivers/addenda issued to SGE members to NIH Ethics Counsel, OGC/ED.

6. Program Staff, Review Staff, and Grants Management Staff

a. Provide guidance, in their respective areas of authority, as appropriate, to assist SGE advisory committee members in avoiding participation in real or apparent conflict of interest situations.

b. In their respective areas of authority, remain alert to SGE advisory committee members' possible conflict of interest situations, and advise and assist CMO, Executive Secretary, and other officials with responsibilities for reviewing OGE 450 forms and Certifications about these concerns.

7. Program/Project Review and Management

All NIH advisors participating in the peer review of applications and/or discussions of program or project concept development or concept clearance are required to certify at the meeting their avoidance of real and apparent conflicts of interest. Refer to <u>NIH Manual 1805</u>, "Use of Advisors in Program and Project Review and Management" for additional guidance.

8. SGE Advisory Committee Members

a. Ensure timely appointment to advisory committee by promptly completing OGE 450 and HHS-697 forms upon receipt. Return completed forms to IC CMO, along with other required appointment documents.

b. Upon receipt, current members promptly review most recent Recusal List, and complete "Verification of Review of Financial Interests" form (see <u>Appendix 5</u>) prior to each meeting, identifying any changes in financial interests. Return completed Verification form to CMO.

c. Complete Certification at each meeting, acknowledging avoidance of real and apparent conflicts of interest by leaving the meeting room during the individual discussion with which they may have an actual or apparent conflict of interest.

G. Implementation:

1. Overview

The Office of Government Ethics, HHS, and NIH require that individuals who are appointed to serve as SGE advisory committee members disclose certain financial interests prior to their appointment or participation. They are also required to update this information prior to each meeting in accordance with established procedures described below, beginning with G.3.

All new SGE advisory committee members must file an OGE 450 form to determine actual or apparent conflicts between the members' public responsibilities and private interests and activities. Supplemental instructions require members to report the source of any non-Federal support available for research endeavors through research or training grants, cooperative agreements, or contracts. Reporting should also be made for funds that are available to a spouse, minor child, or close professional associate for research activities. (See Appendices 2 and 2a.) In all cases, a member's appointment is contingent upon approval of their completed OGE 450 form.

Authority to review and approve OGE 450 forms for SGE advisory committee members, and to issue waivers and authorizations, within their respective organizations has been delegated to IC Deputy Ethics Counselors (DECs). This authority may not be redelegated.

Federal employees serving as regular or ex officio members of National Advisory Councils and Boards, Program Advisory Committees, and Boards of Scientific Counselors may already have a financial disclosure report (SF 278 form or OGE 450 form) on file with their IC or agency. Membership for Federal employees is contingent upon a review of the report by the respective IC DEC for potential conflicts of interest related to their committee responsibilities. If ex officio members have not filed any form, their agency ethics official must have them complete an SF 278 or OGE 450 form.

The HHS Office of the General Counsel, Ethics Division, also requires all SGE advisory committee members to complete an HHS 697 form. (See <u>Appendix 3</u>.) Information provided will help SGE members and committee staff determine if there is or could be a violation or potential violation of the restrictions of the Emolument Clause of the U. S. Constitution. Please see Section I. for procedures.

2. Procedures for Prospective SGE Advisory Committee Members

a. Upon approval of nomination, CMO sends a Letter of Invitation and appropriate appointment forms, including the OGE 450 and HHS 697 forms, with additional instructions and guidance (see Appendices <u>5a</u>, <u>5b</u>, <u>5c</u>, and <u>5d</u>), to prospective SGE advisory committee member. An Administrative Fact Sheet (see <u>Appendix 8</u>) which provides instructions for completing the form, and Supplemental Instructions for Reporting Non-Federal Research/Training Support on the OGE 450 form are also provided. (See <u>Appendices 2 and 2a</u>)

b. Prospective SGE advisory committee member completes, signs, and returns OGE 450 form, along with other appointment documents.

c. CMO reviews OGE 450 form for completeness, returning incomplete form to prospective SGE or contacting prospective SGE to obtain additional required information.

d. ICMO reviews completed OGE 450 form and other disclosures, e.g., CV, Foreign Activities Questionnaire, to identify the SGE's financial interests and covered relationships. For easy identification of section 208 financial interests versus section 2635.502 covered relationships (see <u>Appendix 9</u>), CMO records financial interests and covered relationships that could pose a conflict on a Recusal List (see <u>Appendix 6</u>), under the appropriate heading. (The member's financial interests that do not fall into either category present no conflicts, so no action is required.)

e. CMO, in consultation with Executive Secretary, reviews the OGE 450 form and Recusal List and determines if an initial waiver (see <u>Appendix 4</u>), or in some cases, an authorization (see <u>Appendix 7</u>), is required. Prepare initial waiver where applicable, for signature of Executive Secretary, listing all financial interests, except primary employment and covered relationships noted on the Recusal List. (See <u>Appendix 6</u>.) If appropriate, CMO prepares an authorization to permit SGE to participate in a specific party matter involving an entity with which the SGE has a covered relationship.

f. CMO sends OGE 450 form, new waiver, and Recusal List to appropriate IC Deputy Ethics Counselor for review and signature.

g. CMO sends a copy of each signed waiver to the Ethics Counsel, NIH, and retains original waiver in the CMO office official files with (but not attached to) the SGE advisory committee member's OGE 450 form.

h. CMO, in consultation with Executive Secretary, ensures that SGE advisory committee member is advised to recuse from matters that pose an actual or apparent conflict.

i. CMO gives a copy of Recusal List to the SGE advisory committee member and Executive Secretary before the meeting begins to ensure compliance.

NOTES:

(1) Waivers and the Recusal List apply to all particular matters scheduled for discussion at open and closed sessions of advisory committee meetings. Particular matters may be general or specific, and involve deliberation, decision and/or action. Examples include: grants, contracts, licenses, patents, lawsuits, and policy-making.

(2) New SGE members will be formally appointed only after clearance of OGE 450 form and completion of other aspects of the appointment process.

(3) A new OGE 450 form is not required for members being reappointed to the same committee, e.g., reappointments to Chair; reappointments from a partial term to a full term, provided the total service does not exceed six years and there is no break in service. However, reappointed members are required to continue updating their form prior to each meeting.

3. Procedures for Current SGE Advisory Committee Members

a. CMO sends a blank *Verification of Review of Financial Interests* (see Appendix 5) to SGE advisory committee members prior to each advisory committee meeting, along with additional instructions and guidance (see Appendices 5a, 5b, 5c and 5d), a copy of their OGE 450 form and the most recent Recusal List. (See Appendix 6.) SGE members review their financial interests and update them on the Verification form to reflect any changes that have occurred up to 30 working days prior to the date of the meeting for those members serving on one advisory committee, or up to 45 working days for members serving on two advisory committees at the same time. If an advisory committee meets twice within 45 days, the Verification documentation may be used for both meetings. SGE signs the Verification form, and returns it to CMO.

b. CMO, in consultation with Executive Secretary, reviews the Verification form and determines whether there are any new financial interests or covered relationships that pose potential conflicts of interest or appearance problems. For easy identification of section 208 financial interests versus section 2635.502 covered relationships, CMO records financial interests and covered relationships on a new Recusal List (even if there are no changes), under the appropriate heading. (See Appendices <u>6</u> and <u>9</u>.) When applicable, prepares new waiver or addendum (see Appendix <u>4b</u>) for signature by the Executive Secretary, listing all financial interests, except the primary employment and covered relationships noted on the Recusal List. If appropriate, CMO prepares an authorization to permit SGE to participate in a specific party matter involving an entity with which the SGE has a covered relationship.

c. CMO completes tracking form, "Clearance Process to Identify and Resolve Potential Conflicts of Interest," for SGE Advisory Committee Members, attaching new waivers, addenda, and updated Recusal Lists. (See <u>Appendix 14</u>.)

d. CMO transmits tracking form and updated forms to Executive Secretary for review and signature, and then forwards to appropriate IC Deputy Ethics Counselor for review and signature.

e. CMO retains original waivers and addenda with (but not attached to) the SGE advisory committee member's OGE 450 and Verification forms, and sends a copy of each newly signed waiver and addendum to the Ethics Counsel, NIH.

f. CMO, in consultation with Executive Secretary, ensures that SGE advisory committee member is advised to recuse from matters that pose an actual or apparent conflict.

g. CMO gives a copy of the most recent Recusal List to the SGE advisory committee member and Executive Secretary before the meeting begins to ensure compliance.

4. Procedures for NIH Employees Serving as Regular Members of NIH Advisory Committees

CMO notifies IC DEC of those NIH employees who serve as regular members of NIH advisory committees, and sends a copy of committee charter to IC DEC.

NOTE: IC DEC is the DEC from the advisory committee member's home institute.

a. If member has a SF 278 form on file:

(1) IC DEC reviews form and any recusals/disqualifications or waivers for potential conflicts of interest due to committee responsibilities.

(2) IC DEC returns copy of SF 278 to employee, along with memo stating that recusals/disqualifications and waivers continue to apply in relation to committee responsibilities.

(3) IC DEC forwards copy of member's current recusals/ disqualifications and waivers to CMO.

(4) IC DEC maintains SF 278 form and related documentation.

(5) CMO obtains member's signature prior to each meeting, acknowledging that current recusals and waivers remain in effect regarding matters before the committee (see <u>Appendix 10</u>) and his or her obligation to recuse from matters involving or affecting his or her financial interests unless a waiver or authorization has been issued.

(6) CMO retains original acknowledgment.

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(7) Ethics Counsel, NIH, reviews SF 278 forms filed by the Director, NIH, the Director, NCI, and other IC Directors who serve as DECs and as regular members of NIH advisory committees.

b. If member has an OGE 450 form on file:

(1) IC DEC transmits copy of form to CMO.

(2) CMO reviews, maintains, and updates according to prescribed procedures in section 3.a., EXCEPT Federal members do <u>not</u> receive a waiver/authorization (except in consultation with IC DEC).

(3) CMO obtains member's signature prior to each meeting, acknowledging that current recusals and waivers remain in effect regarding matters before the committee (see <u>Appendix 10</u>) and their obligation to recuse from matters involving or affecting their financial interests unless a waiver or authorization has been issued.

(4) CMO retains original acknowledgment.

c. If member does not have a SF 278 or OGE 450 form on file:

(1) Member must complete OGE 450 form.

(2) CMO reviews, maintains, and updates according to prescribed procedures in section 3.a., EXCEPT Federal members do <u>not</u> receive a waiver/authorization (except in consultation with IC DEC).

(3) CMO obtains member's signature prior to each meeting, acknowledging that current recusals and waivers remain in effect regarding matters before the committee (see <u>Appendix 10</u>) and his or her obligation to recuse from matters involving or affecting his or her financial interests unless a waiver or authorization has been issued.

(4) CMO retains original acknowledgment.

5. Procedures for non-NIH Federal Employees Serving as Regular Members of NIH Advisory Committees

CMO requests SF 278 or OGE 450 forms for non-NIH Federal employees serving as regular members on NIH advisory committees from their respective agencies.

NOTE: The Office of Government Ethics advises that SF 278 forms from other agencies must be marked "Confidential-Not for Public Release," and maintained like the OGE 450 forms. The SF 278 forms may be requested from the members' home agency.

NOTE: IC DEC is the DEC for the advisory committee.

a. If member has a SF 278 form on file:

(1) CMO forwards form to IC DEC for review.

(2) IC DEC returns SF 278 form to CMO for filing.

(3) CMO obtains member's signature prior to each meeting, acknowledging that current recusals and waivers remain in effect regarding matters before the committee (see <u>Appendix 10</u>) and his or her obligation to recuse from matters involving or affecting his or her financial interests unless a waiver/authorization has been issued permitting participation in committee matters.

(4) CMO retains original acknowledgment.

b. If member has an OGE 450 form on file:

(1) CMO reviews, maintains, and updates prior to each meeting according to prescribed procedures in section 5.a.

(2) CMO obtains member's signature prior to each meeting, acknowledging that current recusals and waivers remain in effect regarding matters before the committee (see <u>Appendix 10</u>) and his or her obligation to recuse from matters involving or affecting his or her financial interests unless a waiver/authorization has been issued permitting participation in committee matters.

(3) CMO retains original acknowledgment.

c. If member does not have a SF 278 or OGE 450 form on file:

(1) Member must complete OGE 450 form.

- (2) CMO forwards form to IC DEC for review.
- (3) IC DEC reviews OGE 450 form and returns original to CMO.

(4) CMO reviews prior to each meeting according to prescribed procedures in section 5.a.

(5) CMO obtains member's signature prior to each meeting, acknowledging that current recusals and waivers remain in effect regarding matters before the committee (see <u>Appendix 10</u>) and his or her obligation to recuse from matters involving or affecting his or her financial interests unless a waiver/authorization has been issued permitting participation in committee matters.

(6) CMO retains original acknowledgment.

6. Procedures for Federal Non-NIH Ex Officio Members Serving on NIH National Advisory Councils (NACs) and Program Advisory Committees (PACs)

a. ICMO sends letter (see <u>Appendix11</u>) to new ex officio advisory committee member informing him or her that he or she must submit a copy of his or her financial disclosure form (SF 278 or OGE 450) that is on file with his or her home agency before serving on a Federal advisory committee. This requirement also applies to alternate ex officio members serving in the member's absence.

NOTE: NIH does not have authority to request an ex officio from another agency to complete an OGE 450 form if he or she does not have one on file. In this instance, the CMO may contact the ex officio member's home agency ethics official to request that the member complete an OGE 450 form.

b. CMO reviews ex officio member's SF 278 or OGE 450 form in relation to committee responsibilities and meeting agenda. The home agency will not have ready access to this information and would nevertheless be less-equipped than NIH officials to identify potential conflicts of interest.

c. CMO requests ex officio member's home agency ethics official to prepare waiver, when necessary. Only the home agency has authority to grant waivers to ex officio members. If a conflict is identified based upon review of the ex officio member's SF 278 or OGE 450, the home agency must issue the waiver, or the ex officio member must recuse him or herself from participating in the particular matter(s) with which he or she has the conflict(s).

d. If ex officio members or their alternates do not submit their financial disclosure forms for review prior to the advisory committee meeting, they must certify at the meeting by signing the Conflict of Interest Certification (see <u>Appendix 12</u>) that they did not participate in any matters in which they may have been in conflict. These instances should be unique and infrequent.

In these isolated cases, the certification can be used only once by the ex officio member. It is used because the member's expertise is absolutely required at the particular meeting.

In these instances, ex officio members or alternates must submit a copy of their financial disclosure form immediately following the meeting. CMOs retain these forms in their official files for OGE 450s or SF 278s. SF 278 forms from other agencies must be marked "Confidential-Not for Public Release," and maintained like the OGE 450 forms. The SF 278 forms may be requested from the members' home agency.

7. Procedures for Review of OGE 450 and Verification Forms

a. CMO reviews the OGE 450 and Verification forms for completeness, promptly returning incomplete forms to the submitter, or making annotations based on additional information from the submitter.

In sections for which there is no information, prospective or current advisory committee member must check "NONE" or the equivalent; blank spaces are not acceptable. The exception is Part V, which should be left blank because it is not applicable.

b. Executive Secretary reviews all new OGE 450 forms and Verification forms submitted by prospective or current SGE advisory committee members on their committees, giving particular attention to the members' committee responsibilities in relation to employment and financial interests, and other relationships.

c. CMO prepares Recusal List (see <u>Appendix 6</u>) and, in consultation with Executive Secretary, advises IC DEC of potential conflicts of financial interest and appearance concerns.

d. Executive Secretary in consultation with IC DEC advises prospective member of the various remedial actions available with respect to certain financial interests, when an actual or apparent conflict of interest has been identified, so that committee membership or continued membership may become possible. These remedial actions include, as appropriate:

(1) Issuance of a waiver under 18 U.S.C. § 208(b) (see section 8.a. below);

- (2) Disqualification (recusal) from matters specifically involving or affecting those interests;
- (3) Voluntary resignation, or transfer to another committee; or
- (4) Issuance of an authorization (see Appendix 7) under 5 CFR section 2635.502 (See section 9 below for

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procedures.)

In addition, in rare instances, in order for a member to serve, remedial actions may include:

(5) Divestiture of a conflicting interest;

(6) Resignation from a position with a non-Federal business or other entity; or

(7) Establishment of a qualified blind or diversified trust

e. IC DEC signs the OGE 450 forms as approving official, after all potential conflicts of interest and appearance problems are resolved through one or more of the above remedial actions.

The OGE 450 form (see <u>Appendix 2</u>) includes two signature blocks for review and approval. Persons delegated the authority listed above must sign as the second-level reviewing official ("Agency's Final Reviewing Official"). The first-level (or intermediate) reviewing official may be the Executive Secretary or another designated official.

f. CMO ensures that the OGE 450 and HHS 697 forms are returned to any individual who is not officially appointed. The appropriate IC official documents for the record the reasons why the individual was not officially appointed.

8. Procedures for Issuance of Waivers

a. SGEs: Authority 18 U.S.C. § 208(b)(3)

(1) Criminal conflict of interest statutes preclude SGE advisory committee members from personally and substantially participating as Government employees in any particular matter in which, to their knowledge, they, their spouse, minor child, partner, or an organization with which they are seeking employment or that they serve as an officer, director, trustee, general partner, or employee has a financial interest.

(2) A waiver is a mechanism to resolve an actual conflict of interest. For SGE advisory committee members, a waiver may be granted by the SGE's appointing authority based on the need for the individual's services. Specifically, a waiver under 18 U.S.C. § 208(b)(3) can be granted only when the need for the members' services outweighs the potential for a conflict of interest created by the financial interest involved. (See <u>Appendix 4</u>.)

(3) SGE advisory committee members who would otherwise be disqualified by 18 U.S.C. § 208(a) may be permitted to participate in certain particular matters only if they are granted an individual waiver issued under U.S.C. § 208(b)(3), prior to their participation.

NOTE: Final approval and signature on any required waivers or addenda has been delegated to DECs and may not be redelegated.

b. Federal Employees: Authority 18 U.S.C. § 208(b)(1)

All Federal employees who serve on advisory committees as either appointed members or ex officio members, who would otherwise be disqualified, may participate in certain particular matters only if they are granted an individual waiver issued under 18 U.S.C. § 208(b)(1), prior to the advisory committee member's participation, if the employee's appointing authority determines that the financial interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from the employee. (See Appendix 4a.)

NOTE: Federal employees having relevant waivers for general party matters and recusals in effect when appointed to an advisory committee will not require an additional 208(b)(1) waiver in order to participate in committee matters.

NOTE: NIH does not have the authority to grant waivers to ex officio advisory committee members. If a conflict is identified, the home agency must issue the waiver, or the ex officio member must recuse their self from participating in matters with which they have the conflict(s).

9. Procedures for Granting an Authorization Under 5 CFR Section 2635.502

a. An appearance of a conflict of interest arises where a member participates in a specific party matter (see Definitions in <u>Appendix 1</u>) involving outside parties (including individuals, corporate entities, etc.) with which the member is deemed, by law, to have a covered relationship, and the circumstances are such that a reasonable person with knowledge of the relevant facts would question the SGE's impartiality in the matter.

Covered relationships include:

(1) A person of the member's household, e.g., domestic partner, or a relative with whom the member has a close personal relationship;

(2) A person with whom the member has or seeks a business, contractual, or other financial relationship that involves other than a routine consumer transaction;

(3) Any organization/person for whom the member's spouse, parent or dependent child is, to the member's knowledge, serving or seeking to serve as an officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee;

(4) Any organization/person for whom the member has, within the last year, served as an officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee, including any institution which paid an honorarium to the member; or

(5) Any organization in which the member is an active participant.

b. IC DEC determines whether the member should be authorized to participate in the matter. The IC DEC may determine that the member's impartiality is likely to be questioned and the member should not participate in the matter, or that the risk that any question of impartiality will arise is insignificant and an authorization should be given, allowing the SGE to participate in the specific party matter affecting the person/entity with which the member has a covered relationship. (See <u>Appendix 7</u>.)

c. IC DEC must determine that, in light of all relevant circumstances, the interest of the Government in the member's participation outweighs the concern that a reasonable person may question the integrity of the agency's programs and operations.

Factors that may be considered:

(1) The nature of the relationship involved;

(2) The effect that the resolution of the matter would have upon the financial interests of the person involved in the relationship;

(3) The nature and importance of the member's role in the matter, including the extent to which the individual is called upon to exercise discretion in the matter;

(4) The sensitivity of the matter;

(5) The difficulty of reassigning the matter; and

(6) Adjustments that can be made in the member's duties that would reduce or eliminate the likelihood that a reasonable person would question the member's impartiality.

d. The authorization shall be documented in writing.

10. Availability of "Confidential Financial Disclosure Report" (Forms OGE 450) and Related Documents

ICs may order supplies of OGE 450 forms through the General Service Administration's (GSA) Federal Supply Service, National Stock Number 7540-01-351-9173, or they may reproduce the form from the following web sites:

- http://www3.od.nih.gov/cmo/
- http://ethics.od.nih.gov/

ICs may also reproduce HHS-697 forms from the above web sites.

H. Multi-Campus Institutions:

1. Private Institutions and Affiliates

This section applies ONLY to private institutions and affiliates.

a. An SGE advisory committee member who is employed by a private institution may participate in the review of a grant application submitted by an affiliate of the private institution if the SGE:

- (1) does not hold a joint appointment with that affiliate;
- (2) does not have affiliate-wide responsibilities; and
- (3) has a waiver to do so.

For example, a professor at Harvard may review a grant application from Beth Israel, a Harvard affiliate, if that professor does not hold a joint appointment with Beth Israel, does not have affiliate-wide responsibilities, and has a waiver which states the following:

Additionally, I recommend that you grant [name of individual] a waiver that would allow this individual to participate

in specific matters that may affect any of the affiliates of [name of institution]. I believe that such a waiver is appropriate because [name of individual] does not hold any joint appointments with the affiliates and has no affiliate-wide responsibilities.

b. An SGE advisory committee member who holds a joint appointment at a private institution and at one of its affiliates may participate in a review of a grant application submitted by another affiliate if the SGE:

- (1) does not hold an appointment with the affiliate that has submitted the grant application;
- (2) does not have affiliate-wide responsibilities; and
- (3) has a waiver to do so.

For example, a doctor at Harvard Medical School who also holds an appointment at Massachusetts General Hospital, a Harvard affiliate, may review a grant application submitted by Beth Israel if the doctor does not hold an appointment with Beth Israel, does not have affiliate-wide responsibilities, and has a wavier which states the following:

Additionally, I recommend that you grant [name of individual] a waiver that would allow this individual to participate in specific matters that may affect any other of the affiliates of [name of institution]. I believe that such a waiver is appropriate because [name of individual] does not hold any joint appointments with any other affiliate and has no affiliate-wide responsibilities.

At meetings when applications are reviewed in groups without discussion, i.e., "en bloc" concurrences, the vote of an individual member does not apply to applications from private institutions and any affiliate in which the member holds an appointment or is otherwise in conflict.

2. State Multi-Campus Institutions

This section applies ONLY to State multi-campus institutions.

An SGE advisory committee member who is employed at one university of a State multi-university system may participate in any particular matter affecting another university of the same system, provided the member has no multi-campus responsibilities.

Example 1: An SGE member of an NIH advisory council is from California (Cal) State Fullerton. The SGE **may** participate in formulating the committee's recommendation to award a grant to a researcher at another university of the California State University system, so long as the SGE's employment at Cal State Fullerton entails no multi-campus responsibilities.

Therefore, with this recent OGE guidance and contrary to previous regulations, the separate universities of the California State system are now considered separate entities in the same way as the separate universities of the University of California system had been, under 45 CFR Part 73, Subpart J. However, the separate campuses **within**, for example, Cal State Fullerton, are not considered separate entities for purposes of this policy.

Example 2: A member of the Board of Regents at a State university is asked to serve on an advisory committee established by the National Institutes of Health to consider applications for grants for human genome research projects. An application from another university that is part of the same State system will be reviewed by the committee. Unless he receives an individual waiver under section 208(b)(1) [for Federal employees] or (b)(3) [for SGEs], the advisory committee member **may not** participate in matters affecting the second university that is part of the State system because as a member of the Board of Regents, he has duties and responsibilities that affect the entire State educational system.

I. Emoluments Clause of the U.S. Constitution:

Without consent of Congress, the Emoluments Clause of the U.S. Constitution (Article I, Section 9, Clause 8) prohibits Government employees (interpreted to include SGE advisory committee members) from receiving any present, emolument, office, or title of any kind whatsoever from a foreign state. Also, SGEs cannot accept concurrent outside employment with a foreign government or a political subdivision of a foreign government, including certain public universities or commercial enterprises owned or operated by a foreign government. An emolument includes without limitation any gift, salary, honoraria, transportation, per diem allowances, household goods shipment costs, and housing allowances. The Emoluments Clause applies at all times during the SGE's advisory committee appointment.

Under the statutory provision of the Foreign Gifts and Decorations Act (FGDA), Federal employees, including advisory committee members, may accept items from a foreign government that do not exceed "minimal value" (currently \$305). This figure is adjusted periodically for inflation. Minimal value gifts under the FGDA are gifts to which Congress consented, thus acceptance of such gifts would not violate the Emoluments Clause. The Act authorizes acceptance of items over minimal value when the items consist of an educational scholarship, medical treatment, or expenses for travel taking place entirely outside the United States, thus permitting hotel and meal reimbursements in the foreign country, but not airfare for flights originating or terminating in the United States. If an SGE member participates in an activity with a foreign government on behalf of their university, the foreign government may reimburse the university directly for the individual's expenses, including travel originating and terminating in the United States.

The FGDA's limitation on gifts extends to family members of Federal employees, including advisory committee members. However, family members may accept titles, offices, or positions from foreign government entities, and may accept employment compensation and benefits.

To help SGE members and committee staff determine if there is or could be a violation or potential violation of the restrictions of the Emoluments Clause, the HHS Office of the General Counsel, Ethics Division, issued a mandatory HHS-697 form, that must be completed by all SGE advisory committee members. (See <u>Appendix 3</u>.)

1. Procedures for Prospective SGE Advisory Committee Members

a. CMO includes HHS-697 form, with appointment package, as described in the Administrative Fact Sheet for Special Government Employees (see <u>Appendix 8</u>), and additional instructions and guidance. (See Appendices <u>5b</u> and <u>5d</u>.)

b. CMO reviews and, when necessary, advises Executive Secretary and IC DEC of violation or potential violation of Emoluments Clause restrictions.

c. CMO consults with NIH Ethics Counsel if unable to determine, after careful analysis, if violation or potential violation exists.

d. CMO, after consultation with IC DEC or NIH Ethics Counsel, informs Executive Secretary if a violation is identified and advises that 1) the member must terminate their foreign activity(s), or 2) they must decline appointment to serve on the advisory committee.

2. Procedures for Current SGE Advisory Committee Members

a. CMO sends HHS-697 form to members, with additional instructions and guidance (see Appendices <u>5b</u> and <u>5d</u>.), prior to the first committee meeting of each calendar year. The form should be forwarded with the OGE 450 update/verification of financial interests.

b. CMO reviews and, when necessary, advises Executive Secretary and IC DEC of violation or potential violation of Emoluments Clause restrictions

c. CMO consults with NIH Ethics Counsel if unable to determine, after careful analysis, if violation or potential violation exists.

d. CMO, after consultation with IC DEC or NIH Ethics Counsel, informs Executive Secretary if a violation is identified and advises that 1) the member must terminate their foreign activity(s), or 2) they must terminate their service on the advisory committee.

<u>J. Annual Ethics Training Requirement:</u> Office of Government Ethics regulations (5 C.F.R. Part 2638 Subpart G, dated April 7, 1992; amended in 1997 and published in the Federal Register on March 12, 1997) require that all Federal employees, including SGEs, who are required to file confidential financial disclosure reports (OGE 450 and SF 278) receive annual ethics training.

Office of the General Counsel, Ethics Division, HHS (OGC/ED/HHS) is responsible for approving the content of annual training programs and providing training information and guidance to DECs for use in developing internal training programs.

SGE advisory committee members may meet the annual training requirement by reading written materials such as the Ethics Rules for SGEs, provided by the OGC/ED/HHS. (See <u>Appendix 13</u>.) The format and type of training, e.g., videotapes, computer-based training, for NIH employees who are filers with advisory committee responsibilities is determined by the IC DEC that employs the individual.

Additionally, each year as a part of the annual ethics training, committee members receive a copy of a notice informing committee members associated with law, public relations, lobbying, or accounting firms that they are prohibited from receiving compensation as a result of their firm representing a specific client on a particular matter which is the subject of a committee's meetings. (See <u>Appendix 13a</u>.)

CMOs are required to maintain documentation that training material was sent, the website address for reviewing electronic training materials was provided, or that in-person training was held for the SGE advisory committee members.

K. Confidentiality: Information provided on the OGE 450 form is maintained under Privacy Act System Notice OGE/GOVT-2, "Confidential Statements of Employment and Financial Interest." The Privacy Act of 1974 (5 U.S.C. § 552a) gives the subject individual right of access upon request and limits disclosure to the public except by court order or by request of the U.S. Congress, by the General Accounting Office as part of a Federal agency audit, or as otherwise provided under the Privacy Act.

L. Records Retention and Disposal: Records pertaining to financial disclosure and foreign activities are maintained in locked file cabinets and are retained and disposed of under the authority of <u>NIH Manual 1743</u>, "Keeping and

IC Committee Management Offices are responsible for retaining original copies of all OGE 450 forms and HHS 697 forms for a minimum of six years after the member's term ends, except that documents needed in an on-going investigation will be retained until no longer needed in the investigation.

OGE 450 forms are confidential and shall not be released to the public except pursuant to court order, by request of the U.S. Congress, by the General Accounting Office as part of a Federal agency audit, or as otherwise provided under the Privacy Act.

"Public Financial Disclosure Report" SF 278 forms received from other agencies must be marked "Confidential-Not for Public Release," and maintained like the OGE 450 forms. The SF 278 forms are publicly available at the members' home agencies.

All other records including report of meeting arrangement sheets or lists that contain information regarding conflicts of interest, individual pre-meeting and committee post-meeting Conflict of Interest and Confidentiality Certification Forms and other supporting papers pertinent to the meetings of the committee. Destroy when 10 years old, except as needed in an ongoing investigation and until investigation is completed.

NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over 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 <u>IC Records Officer</u> 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, 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 Congressional oversight committees if requested and are subject to 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.

<u>M. Management Controls</u>: The purpose of this chapter is to set forth policy and procedures to avoid the occurrence of conflicts of interest or the appearance of such conflicts, among Special Government Employees appointed as members of NIH Federal advisory committees subject to the Federal Advisory Committee Act. It also provides conflict of interest procedures for Federal employees who may serve as regular appointed members or ex officio members on NIH Federal advisory committees.

1. Office Responsible for Reviewing Management Controls Relative to this Chapter:

The Office of Federal Advisory Committee Policy (OFACP), IC Deputy Ethics Counselors (DECs), and Ethics Counsel, NIH.

Through this manual issuance, the OFACP in the Office of the Director, NIH, is accountable for ensuring that CMOs have implemented appropriate management controls.

2. Frequency of Review:

OFACP staff conduct ongoing as well as biennial reviews, as described below, of CMO files. Annual ethics training is also provided to the CMOs.. In addition, the Office of Government Ethics, at their discretion and in their time frame, may audit any or all of the ICs within NIH. An ongoing review schedule from 1-3 years will be established for the NIH Office of Management Assessment to do an internal review to determine IC compliance with the policy.

3. Method of Review:

The procedures implemented in this chapter receive an ongoing review by the Office of Federal Advisory Committee Policy during monthly meetings with IC CMOs, and through continuous individual discussions between OFACP staff and IC CMOs. The OFACP staff also maintain appropriate oversight through biennial reviews of CMO procedures and files. Evaluation of the compliance with the policy is conducted using a sample of members to ensure that all ethics requirements are being adhered to by the CMOs. Problem issues identified by the reviewers are brought to the attention of the Director, OFACP, and are again reviewed for compliance within a reasonable time. Additional training is provided, as necessary, and issuance of interim policies and procedures, as required.

Additionally, the Director, OFACP and senior staff maintain open communications with NIH ethics staff and colleagues of other Federal agencies for best practices. Recommendations for program improvements are made when appropriate.

4. Review Reports:

Reviewers send their reports to the Director, OFACP, and when appropriate, the IC DECs and Ethics Counsel, NIH, indicating that controls are in place and working well, or include any management control issues that should be brought to the attention of the report recipients.

APPENDICES

APPENDIX 1: Definitions

1. Actual Conflict of Interest

Members of National Advisory Councils and Boards, Program Advisory Committees, Boards of Scientific Counselors, including Federal employees and other individuals who serve as SGEs, are prohibited by criminal statute, 18 U.S.C. § 208(a), from participating personally and substantially in an official capacity in any particular matter in which, to their knowledge, they or any person whose interests are imputed to them has a financial interest, if the particular matter will have a direct and predictable effect on that interest. The financial interests of the following persons (and organizations) are considered imputed: the member's spouse; minor child; general partner; an organization or entity for which the member serves as officer, director, trustee, general partner or employee; and a person (organization) with whom the member is negotiating for or has an arrangement concerning prospective employment.

2. Appearance of a Conflict of Interest

An appearance of a conflict of interest arises where an advisory committee member is involved in a particular matter involving specific outside parties (including individuals, corporate entities, etc.) and the circumstances are such that a reasonable person with knowledge of the relevant facts would question the advisory committee member's impartiality in the matter because the member is deemed by law to have a covered relationship with a party to the matter.

A member has an apparent conflict of interest if the matter involves:

(1) a person or organization, other than a prospective employer, with whom the SGE member has or seeks a business, contractual, or other financial relationship that involves other than a routine financial transaction (e.g., person or organization which gives or awards to members or their non-Federal employing institutions a research or training grant or award);

(2) a person who is a member of the advisory committee member's household other than spouse or minor child, e.g. domestic partner, or who is a relative with whom the advisory committee member has a close personal relationship;

(3) a person or organization for whom the member's spouse, parent, or dependent child is, to the member's knowledge, serving or seeking to serve as an officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee;

(4) any person or organization for whom the member has, within the last year, served as an officer, director, trustee, general partner, agent, attorney, consultant, contractor, employee (including advisor, researcher, trainee), expert, or speaker

(5) any organization, other than a political party, in which the member is an active participant; and/or

(6) any person or organization where the member is concerned that circumstances would raise a question about the member's impartiality in the performance of Government activities.

3. Authorization

An authorization is a mechanism used to resolve an appearance of a conflict of interest. An advisory committee member must obtain an authorization under 5 CFR 2635.502 where the "employee knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member of his or her household, or knows that a person with whom he or she has a covered relationship is or represents a party to such a matter, and where the employee determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question his or her impartiality in the matter, the employee should not participate in the matter until he or she has informed the agency designee of the appearance problem and received authorization from the agency designee..." (5 CFR 2635.502(a)) (See <u>Appendix 7</u>.)

4. Covered Relationship

A term used to describe relationships that do not constitute financial interests, but which may cause a reasonable person to question an employee's impartiality. A covered relationship may be any entity with which an advisory committee member has or seeks a financial, business, or other contractual relationship, such as research funding sources and award sources; any entity the member has served within the last year as officer, director, trustee, general partner, agent, attorney, consultant, contractor, or speaker such as one-time speaking engagements, sources of honoraria from speeches, or consulting as an "independent contractor." A covered relationship also exists with a former employer for one year after leaving. (See <u>Appendix 9</u>.)

5. Direct and Predictable Effect

The term "direct and predictable effect" refers to the impact an advisory committee member's official duties may have on an outside financial interest. A particular matter will have a direct effect on a financial interest if there is a close causal link between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest. An effect may be direct even though it does not occur immediately. A particular matter will not have a direct effect on a financial interest, however, if the chain of causation is attenuated or is contingent upon the occurrence of events that are speculative or that are independent of, and unrelated to, the matter. A particular matter will have a predictable effect if there is a real, as opposed to a speculative, possibility that the matter will affect the financial interest. It is not necessary, however, that the magnitude of the gain or loss be known, and the dollar amount of the gain or loss is immaterial.

6. Emolument

An emolument includes without limitation any gift, salary, honoraria, transportation, per diem allowances, household goods shipment costs, and housing allowances. The Emoluments Clause of the United States Constitution prohibits U.S. Government employees, including SGEs, from receiving any present, emolument, office, or title of any kind from a foreign state. (See Section I.)

7. Employment

Employment includes but is not limited to employment by foreign governments or other entities, summer and part-time employment, membership on boards of organizations, service as an officer, director, or trustee, and consultant appointments, even if unremunerated.

8. Federal Advisory Committee

Any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof, which is established by statute, or established or utilized by the President or any agency official for the purpose of obtaining advice or recommendations on issues, policies, or other matters which are within the scope of his or her responsibilities and are related to the programs, responsibilities or activities of the Department. Excluded from this definition is any committee composed entirely of full-time officers or employees of the Federal Government.

9. Financial Interest

A financial interest, broadly defined, is any potential for **gain or loss** to the advisory committee member or anyone whose interests are imputed to the member (See Definition 1 above). Such financial interests include, without limitation, stock, options, bank accounts, mutual funds, sector funds, consulting relationships, leaves of absence agreements, royalty or licensing agreements, employment agreements, retirement assets, trust holdings, and bonds.

10. Particular Matter

There are two types of particular matters:

- Matters involving specific parties (also known as specific party matters) those matters that are focused on the interests of the United States and one or more identified parties. A grant application is a specific party matter;
- Matters of general applicability (also known as general matters) those matters that will not have a special or unique effect on any particular entity, but will instead have the same effect on all members of a class or group of entities. Consideration of new grant application requirements is an example of a general matter.

11. Personal and Substantial Participation

To participate personally means to participate directly. To participate substantially means that the advisory committee member's involvement is of significance to the matter, even if not decisive.

12. Special Government Employee (SGE)

As defined by 18 U.S.C. § 202(a), an SGE can be an officer or employee of the Executive Branch who is retained, designated, appointed, or employed to perform temporary duties, with or without compensation, for a period not to exceed 130 days during any period of 365 days, either on a full-time or intermittent basis. Members of NIH Advisory Councils and Boards, Program Advisory Committees, and Boards of Scientific Counselors who are not otherwise employed by the Federal Government are appointed as SGEs.

13. Waiver

A waiver is a mechanism used to resolve an actual conflict of interest. An SGE advisory committee member may obtain a waiver under 18 U.S.C. § 208(b)(3) when "the need for the individual's services outweighs the potential for a conflict of interest created by the [otherwise disqualifying] financial interest." (See Appendix 4) Federal employees who are appointed as regular advisory committee members, regardless of whether they file a financial disclosure report OGE 450

or SF 278, may obtain a waiver under 18 U.S.C. § 208(b)(1) when "the employee's financial interest in the particular matter or matters is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from the employee." (See Appendix 4a.)

APPENDIX 2: OGE Form 450, "Confidential Financial Disclosure Report"

<u>APPENDIX 2a:</u> Supplemental Instructions for Reporting Non-Federal Research/Training Support on OGE Form 450

In Part I - Assets and Income

Report the source of any (even if below the \$1,000 asset threshold and the \$200 income threshold indicated on the OGE 450 form) non-federal support (e.g., funds or resources) available for direct support of your research endeavors through research or training grants, cooperative agreements, or contracts. Reporting should also be made for funds that are available to a spouse, minor child, or close professional associate for research endeavors.

You should report the source of any such support that (1) you have received in the past twelve months, (2) you are currently receiving, and (3) you may have pending for review or award.

Report the identity of the organization (including the city and state) of the non-federal research/training support, the type of organization, the identity of the principle investigator, and the dates of the projected support. Note that the amount of the non-federal support need not be reported.

This information will be used by appropriate staff to determine whether this support might be perceived to constitute a real or apparent conflict of interest in the exercise of your duties as a member of an NIH advisory committee.

OFACP 06/17/98 No Change as of 12/31/05

APPENDIX 3: HHS Form 697, "Foreign Activities Questionnaire"

APPENDIX 4: Sample Conflict of Interest Waiver Format for SGE Advisory Committee Members

DATE:

TO: [Name of Employee's Deputy Ethics Counselor or Designee] [Title]

FROM: [Name of Recommending Official] [Title]

SUBJECT: Conflict of Interest Waiver for [Name of Individual]

I am writing to request a waiver for **[name of individual]**, a member of the **[name of advisory committee]**, from the conflict of interest prohibitions of 18 U.S.C. §208(a). Waivers under Section 208(b)(3) may be granted by the appointing official where "the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved" and where the individual has made a disclosure of the financial interests at issue. The Office of the General Counsel has determined that you are the appointing official for purposes of Section 208 in accordance with Executive Order 12731 Section 401. Therefore, you have the authority to grant **[name of individual]** a waiver under Section 208(b)(3).

Section 208(a) prohibits Federal Executive Branch employees, including Special Government Employees, from participating personally and substantially in particular matters in which any of the following individuals or organizations has a financial interest: (1) the employee; (2) the employee's spouse; (3) the employee's minor child; (4) an organization in which the employee serves as an officer, director, trustee, partner, or employee; or (5) a person or organization with which the employee is negotiating for prospective employment or has an arrangement for prospective employment. Since **[name of individual]** is a Special Government Employee, this individual is under a statutory obligation to refrain from participating in any deliberations that involve a particular matter having a direct and predictable effect on a financial interest attributable to this individual.

The member's financial interest subject to waiver are:

Organization Kind of Organization Nature of Interest

The functions of the Committee, as stated in its charter, are to **[add description of committee functions and any specific functions that are pertinent]**. As a member of the **[name of advisory committee]**, **[name of individual]** potentially could become involved in particular matters that affect reported financial interests. Under Section 208, **[name of individual]** is prohibited from participating in particular matters. However, as noted above, you have the authority under 18 U.S.C. § 208(b)(3) to grant a waiver permitting **[name of individual]** to participate in particular

matters as you deem appropriate.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to **[name of individual]** that would allow this individual to participate in the matters identified below.

First, ______. [Describe the nature of the financial interest. For example, the relationship between the financial interest and the actions that the individual may take as a committee member should be explained, e.g., whether the financial interest if likely directly to be affected or if the relationship is more attenuated. Along this line, describe what the individual will be doing on the committee in detail and how this work will not specifically and uniquely affect the employee's financial interests. If the employee's financial interests would be specifically affected, explain the need for a specific waiver and why another individual cannot be found to perform this service.]

Second, the Federal Advisory Committee Act requires that committee memberships be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee. **[Describe the individual's expertise and why the individual's services are essential.]** We believe that this individual's participation in the deliberations of the advisory committee will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant **[name of individual]** a waiver that would allow this individual to participate in general matters that may directly affect the above listed financial interests, but not specific party matters specifically and uniquely affecting these financial interests. I believe that such a waiver is appropriate because in this case, the need for the services of **[name of individual]** outweighs the potential for a conflict of interest created by the financial interest involved.

[Name of Signee]

DECISION:

____ Waiver granted based on my determination, made in accordance with Section 208(b)(3), that the need for the individual's services outweighs the potential for a conflict of interest created by the financial

interest

attributable to the individual.

____ Waiver denied.

[Name of Employee's Deputy Ethics Counselor or Designee]

Date

cc: NIH Ethics Counsel, OGC/ Ethics Division

<u>APPENDIX 4a:</u> Sample Conflict of Interest Waiver Format for Federal Employees Appointed as Regular Advisory Committee Members

DATE:

- TO: [Name of Employee's Deputy Ethics Counselor or Designee] [Title]
- FROM: [Name of Recommending Official] [Title]

SUBJECT: Conflict of Interest Waiver for [Name of Individual]

The purpose of this memorandum is to request that you grant a waiver from the conflict of interest prohibitions of 18 U.S.C. §208(a) for **[name of individual]**, a member of the **[name of advisory committee]**. Waivers under section 208 (b)(1) may be granted by the appointing official when it is determined that "the (disqualifying financial) interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect" from the employee and where the individual has made a disclosure of the financial interests at issue. We have determined that you are the appointing official for purposes of section 208. Therefore, you have the authority to grant **[name of individual]** a waiver under section 208 (b)(1).

[Name of individual] serves as [individual's title]. Section 208(a) prohibits Federal Executive Branch employees

from participating personally and substantially in particular matters that will have a direct and predictable effect on a financial interest of the employee, **[his/her]** spouse, minor child, general partner, or any organization of which the individual is an employee, general partner, officer, director, or trustee.

[Name of individual] has disclosed [his/her] potentially conflicting personal and imputed financial interests as follows:

[Describe the types of financial interests of the individual and the identity of the person whose financial interest is involved, if other than the employee, that may present a conflict of interest. This includes, but is not limited to, interests in real or personal property, stocks, stock options, bonds, job offer, and partnership interests. In addition, describe any entities for which the individual is an officer, director, trustee, general partner, or employee.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to [name of individual] that would allow [him/her] to participate in matters that will affect the above [financial interests, companies/organizations, etc.] to the same extent as they would affect all similarly situated entities.

[Describe the reasons for granting the waiver, focusing on the test, i.e., that the interest is not so substantial as to be deemed likely to affect the integrity of the services that the Government may expect from the individual. Describe the amount of the interest and why it is not substantial.]

In addition, the nature of the duties that **[name of individual]** performs are such that the integrity of **[his/her]** services are not likely to be compromised. The duties involve **[describe]**. Since **[name of individual]** is recused from participating in any deliberations that involve any particular matters that uniquely and distinctly, as well as directly and predictably, affect any of the financial interests described above, the only matters in which **[he/she]** will participate that will affect **[his/her]** financial interests will be those matters that affect the interests of all entities similarly situated to the same extent. While this participation is technically covered by the current interpretation of section 208, it poses far less risk of bias or conflict of interest than participation in matters that relate specifically to a particular entity.

Accordingly, I recommend that you grant **[name of individual]** a waiver that would allow this individual to participate as **[individual's title]** in all matters that may affect entities in which this individual has a personal or imputed interest only to the same extent as they affect all similarly situated entities. I believe that such a waiver is appropriate because in this case, the interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from **[name of individual]**.

[Name of Signee]

DECISION:

Waiver granted based on my determination, made in accordance with section 208 (b)(1), that the interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from such employee.

Waiver denied.

[Name of Employee's Deputy Ethics Counselor or Designee]

[Date]

cc: NIH Ethics Counsel, OGC/ Ethics Division

* NIH officials do not have statutory authority to grant waivers to employees of other HHS components or other Federal departments or agencies.

APPENDIX 4b: Sample Addendum to Conflict of Interest Waivers

ADDENDUM TO CONFLICT OF INTEREST WAIVER

NAME OF MEMBER: [Name of Individual]

ADVISORY COMMITTEE: [Name of Advisory Committee]

DATE OF ORIGINAL WAIVER: [Date of Waiver]

<u>Organization</u>	Kind of Organization	Nature of Interest
All new items:		
[Name of Compa /Institution	any [e.g., Drug Company] or University]	[e.g., Stock (new) or Professor, (new or left)]

[Describe how the new financial interests identified above may be affected by the work of the committee.]

[Name of Recommending	Date
Official & Signature]	

DECISION: I have read the original waiver issued to this member. Based upon the description therein of the matters handled by this committee and the new financial interest(s) identified above, this:

_____ Addendum to waiver is granted based on my determination, made in accordance with Section 208(b)(1) or 208(b)(3), that the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest attributable to this individual.

Addendum to Waiver denied.

[Name of IC Deputy Ethics Counselor & Signature]

Date

cc: NIH Ethics Counsel, OGC/ED

APPENDIX 5: Sample Verification Review of Financial Interests Form

VERIFICATION OF REVIEW OF FINANCIAL INTERESTS PRIOR TO THE MEETING OF THE

[Name of Committee] [Date of Meeting]

I have reviewed my 1) OGE 450, Confidential Financial Disclosure Report and 2) most recent Recusal List. I find that:

	NO INFORMATION HAS FROM THAT REPORTED PREVIOUSLY	CHANGED	
	INFORMATION HAS CHA WHICH IS REPORTED BE (indicate addition or dele	LOW:	
ORGANIZATION	KIND OF ORGANIZATION	NATURE OF INTEREST (& DATE, if applicable)	ADD/DELETE

(PLEASE INCLUDE UPDATED NON-FEDERAL RESEARCH/TRAINING SUPPORT.)

I CERTIFY THAT THE STATEMENT I HAVE MADE ON THIS FORM AND ALL ATTACHED STATEMENTS ARE TRUE, COMPLETE, AND CORRECT TO THE BEST OF MY KNOWLEDGE.

Signature

Date

(Refer to Privacy Act Statement on page 3 of OGE 450 form.)

APPENDIX 5a: Transmittal Memorandum for Verification of Review of Financial Interests [insert date]

TO: Members, [insert name of committee]

FROM: Committee Management Officer [or appropriate title], [insert IC acronym]

SUBJECT: Update of Financial Interests and/or Institutional Affiliations (OGE-450)

DUE [insert date]

The U. S. Office of Government Ethics (OGE) requires all Special Government Employees (SGEs) serving on NIH advisory committees to complete an OGE 450 form, Executive Branch Confidential Financial Disclosure Report, upon accepting office. SGE must also review and update their financial information within 30 working days before each committee meeting until the completion of their term.

In preparation for the [insert meeting date(s)] meeting, please review and verify the following document(s):

Original OGE 450 form and most recent Recusal List

Please note any **additions or deletions** on the *Verification of Review of Financial Interests* form. For your convenience, presented below are some helpful hints to remember when completing the update.

- <u>One-time events</u> or activities should **include month and year**. Such "one-time" activities may include past speaking engagements, consultant work, or your role in organizational entities, other than those solely of an honorary nature. Recusals required because of these remain in effect for one year.
- **Report earned income over \$200**. Please report sources of earned income such as salaries, fees, and/or honoraria, which generated over \$200 in income during the reporting period. Note that it is not necessary for you to list savings accounts.
- <u>Report assets with a fair market value greater than \$1,000 at the close of the reporting period which produced income over \$200.</u> Assets may include: stocks, bonds, tax shelters, real estate, mutual funds, pensions, annuities, IRAs, trusts, commodity futures, trades and businesses, and partnership interests. When listing mutual fund, please provide the complete name(s) of the fund(s). When listing 401(k), 403(b), 457 or IRA accounts, please provide the complete name of all underlying assets held in these accounts. For example, instead of simply writing "IRA," you must identify the sponsor of the account and its specific Fund name. You must also list whether it is individually managed by you or done professionally.
- **Report any positions, whether or not compensated**. Positions may include: an employee, officer, director, trustee, general partner, proprietor, representative, executor, or consultant for a business, non-profit organization, professional organization, or educational institution.
- <u>Report any non-Federal research/training support</u>. Please report all non-Federal funds or resources for direct support of research or training grants, cooperative agreements, or contracts for you, your spouse, minor child, or close professional associate (even if below the \$1,000 asset threshold and the \$200 income threshold). You do not need to report the amount of the non-Federal support. Reported support should include funds you are currently receiving, have received in the past twelve months, and may have pending for review or award.

After signing, **please return the Verification of Financial Interests form by overnight priority mail no later than [insert day and date].** A Federal Express envelope is enclosed for your convenience. This will ensure adequate time for review and clearance of your updated information before the [insert meeting date] Committee meeting.

We appreciate your patience and willingness to complete this form. Please understand that obtaining this information is required by Federal law and assists us in identifying and avoiding conflicts of interest. The confidentiality of the information you provide will be maintained in a manner consistent with the Privacy Act of 1974, as amended.

If you will not be attending the meeting, it is not necessary for you to complete the verification form. However, please inform us by [insert due date] that you will be absent from the meeting.

If you have any questions or need additional information, please contact me at [insert phone number].

[insert name of signee]

Attachments:

- (1) Copy of original OGE 450 Form
- (2) Most recent Recusal List
- (3) Verification of Financial Interests Form
- (4) Helpful Hints for Completing/Updating OGE 450 Form

<u>APPENDIX 5b:</u> Transmittal Memorandum for Verification of Review of Financial Interests and Foreign Activities

[insert date]

TO: Members, [insert name of committee]

FROM: Committee Management Officer [or appropriate title], [insert IC acronym]

SUBJECT: Update of Financial Interests and/or Institutional Affiliations (OGE-450) and Foreign Activities Questionnaire (HHS-697)

DUE [insert date]

The U. S. Office of Government Ethics (OGE) requires all Special Government Employees (SGEs) serving on NIH advisory committees to complete an OGE 450 form, Executive Branch Confidential Financial Disclosure Report, upon accepting office. SGE must also review and update their financial information within 30 working days before each committee meeting until the completion of their term.

Also, HHS requires SGE advisory committee members to complete the HHS-697 form, AForeign Activities Questionnaire@ yearly during their term of service.

In preparation for the [insert meeting date(s)] meeting, please review and verify the following documents:

Original OGE 450 form and most recent Recusal List

Please note any **additions or deletions** on the *Verification of Review of Financial Interests* form. For your convenience, presented below are some helpful hints to remember when completing the update.

- <u>One-time events</u> or activities should **include month and year**. Such Aone-time@ activities may include past speaking engagements, consultant work, or your role in organizational entities, other than those solely of an honorary nature. Recusals required because of these remain in effect for one year.
- <u>Report earned income over \$200</u>. Please report sources of earned income such as salaries, fees, and/or honoraria, which generated over \$200 in income during the reporting period. Note that it is not necessary

for you to list savings accounts.

- Report assets with a fair market value greater than \$1,000 at the close of the reporting period which produced income over \$200. Assets may include: stocks, bonds, tax shelters, real estate, mutual funds, pensions, annuities, IRAs, trusts, commodity futures, trades and businesses, and partnership interests. When listing mutual fund, please provide the complete name(s) of the fund(s). When listing 401(k), 403(b), 457 or IRA accounts, please provide the complete name of all underlying assets held in these accounts. For example, instead of simply writing AIRA,@ you must identify the sponsor of the account and its specific Fund name. You must also list whether it is individually managed by you or done professionally.
- **Report any positions, whether or not compensated**. Positions may include: an employee, officer, director, trustee, general partner, proprietor, representative, executor, or consultant for a business, non-profit organization, professional organization, or educational institution.
- **Report any non-Federal research/training support**. Please report all non-Federal funds or resources for direct support of research or training grants, cooperative agreements, or contracts for you, your spouse, minor child, or close professional associate (even if below the \$1,000 asset threshold and the \$200 income threshold). You do not need to report the amount of the non-Federal support. Reported support should include funds you are currently receiving, have received in the past twelve months, and may have pending for review or award.

Foreign Activities Questionnaire

- Question 1: Please describe any activities you may have with a foreign government, including a foreign public university or government-owned corporation. Such activities may include consulting work, receipt of grants or contracts, faculty appointment, lectureships, or holding an office, title, or position.
- Question 2: You may be exempt from the Emoluments Clause if you are employed by a foreign public university that is independent of their government. In some cases, the individual school of which you are employed may be independent, even if the university isn=t. For example, your salary may come from a private source. Please answer by asking yourself who manages and controls the funding and terms of your employment.
- Question 3: Please list any tangible gift exceeding the minimal value of \$305 or any emolument that you, your spouse, or dependent child will receive from a foreign government during your term as an advisory committee member. An emolument includes salary, honoraria, transportation, per diem allowances, household goods shipment costs, and housing allowances. Items over minimal value for an educational scholarship, medical treatment, or expenses for travel taking place entirely outside the United States are permissible.
- Question 4: Please describe any lobbying activities you are participating in on behalf of a foreign entity.

After completing and signing, please return the *Verification of Review of Financial Interests* form and *Foreign Activities Questionnaire* by overnight priority mail no later than [insert day and date]. A Federal Express envelope is enclosed for your convenience. This will ensure adequate time for review and clearance of your updated information before the [insert meeting date] Committee meeting.

We appreciate your patience and willingness to complete these forms. Please understand that obtaining this information is required by Federal law and assists us in identifying and avoiding conflicts of interest. The confidentiality of the information you provide will be maintained in a manner consistent with the Privacy Act of 1974, as amended.

If you will not be attending the meeting it is not necessary for you to complete the verification form, however, please complete and return the *Foreign Activities Questionnaire*. Also, please inform us by [insert due date] that you will be absent from the meeting.

If you have any questions or need additional information, please contact me at [insert phone number].

Attachments:

- (1) Copy of original OGE 450 form
- (2) Most recent Recusal List
- (3) Verification of Review of Financial Interests form
- (4) Foreign Activities Questionnaire
- (5) Helpful Hints for Completing/Updating OGE 450 Form
- (6) Special Government Employees and Foreign Activities

<u>APPENDIX 5c:</u> Helpful Hints for Completing/Updating the Confidential Financial Disclosure Report (OGE Form 450)

HELPFUL HINTS

For Completing/Updating the Confidential Financial Disclosure Report (OGE-450)

PART I - Assets & Income

o Report assets with a fair market value greater than \$1,000 at the close of the reporting period or producing income over \$200.

- Assets include stocks, bonds, tax shelters, real estate, mutual funds, pensions, annuities, IRAs, trusts, commodity futures, trades and businesses, and partnership interests.
- Mutual fund accounts must include the complete name of each fund(s). For mutual funds concentrated in a particular economic sector, indicate the industry in which the fund is primarily invested. Examples are attached.

NOTE: Include income and assets of your spouse and dependent children.

o For each asset identified, provide an adequate description and the type of income generated by the asset.

NOTE: Income sources must be listed as well.

o **IRA or Cash Management Account** - Specify the underlying assets in any account which you maintain, including the complete name of an investment fund. You may attach a computer print-out or broker's statement specifying the individual holdings in the portfolio **only** if it clearly gives the required information.

o **TIAA-CREF** - Specify the TIAA-CREF investments in your account (TIAA traditional annuity, TIAA real estate, and CREF and TIAA-CREF mutual funds). If you are invested in any of the CREF and TIAA-CREF mutual funds, you need to specifically identify the mutual fund(s) in which you participate.

NOTE: If a prior employer account you must list in Part IV.

o **401(k) plans** - List the underlying holdings in 401(k) plans (down to the level of individual "funds") or in any pension plans in which you control the investments.

See additional information about pension plans under PART IV below.

o **Stock Holdings & Other Investments** - Indicate the full name of each company. Describe the nature of the business (when it is not otherwise obvious).

o **Earned Income** - Report earned income over \$200 and sources of earned income such as salaries, fees, and/or honoraria. Earned income sources of your spouse must be reported if greater than \$1,000 (greater than \$200 for honoraria). Do not list savings accounts.

• **One-time Activities** - Include the month and year for one-time events or activities. Such one-time activities may include past speaking engagements, consultant work, or your role in organizational entities other than those solely of an honorary nature.

NOTE: Compensated outside positions listed must also be listed in PART III.

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o Report liabilities over \$10,000 owed to any creditor at any time during the reporting period.

PART III - Outside Positions

o **Positions Held** - Report positions, whether or not compensated, which may include: an employee, officer, director, trustee, general partner, proprietor, representative, executor, or consultant for a business, non-profit organization, or educational institution.

o Earned Income - Compensated outside positions listed under PART I must also be listed under PART III.

PART IV - Agreements and Arrangements

o List any continuation of payments, such as severance pay, from your prior employer (other than Federal employment). Also list agreements/arrangements with your former employer such as a leave of absence, continued participation in a benefit or pension plan, etc.

o **Pension Plan** - Indicate whether your pension plan is classified as a *defined contribution plan* or *defined benefit plan* (see below), whether it is independently managed, and whether the plan is invested in the stock of your prior employer. The employee benefits brochure or handbook of your prior employer is usually a source for this information.

o **Defined Contribution Plan** - Former employer does not guarantee your benefits. Your pension is based on your own contributions. Disclose the underlying holdings since each investment is treated as if it is your direct holding.

o **Defined Benefit Plan** - Employer guarantees your benefits through its investments and other holdings. Since the benefits are the employer's obligation/liability, your financial interest is in the employer, not in its investments. Disclose the name of the former employer, but not the underlying holdings of the investments.

PART V - NOT APPLICABLE

ATTACHMENT

SAMPLE

You must specify underlying assets in any reportable IRA or Cash Management Account which you maintain, including the complete name of an investment fund:

Incorrectly Listed

IRA or 401(k)

Correctly Listed

Merrill Lynch IRA which includes:

AT&T Stock

Janus Twenty Fund

Pfizer Stock

You must give the specific name of a fund:

Incorrectly Listed

Fidelity Mutual Funds

Correctly Listed

Fidelity Growth and Income Fund

Fidelity Contrafund

Fidelity Balanced Fund

You must give the specific name of the retirement fund:

Incorrectly Listed

TIAA/CREF

Correctly Listed

TIAA Traditional

υ

TIAA Real Estate

CREF Stock

CREF Global Equities

CREF Equity Index

CREF Growth

CREF Social Choice etc.

APPENDIX 5d: Special Government Employees and Foreign Activities

All U.S. Government employees, including those appointed as Special Government Employees (SGEs), are subject to legal restrictions concerning foreign activities. SGEs are Government employees who are appointed to temporary service on an advisory committee (i.e., NIH Institute/Center Advisory Council, Board of Scientific Counselors, or Program Advisory Committee) or, in some cases, as individual experts or consultants. Although SGEs may spend fewer than 10 days per year in an NIH position, many Government rules apply to them, including the Emoluments Clause of the U.S. Constitution, which may limit acceptance of funds from foreign sources.

As an SGE, you are required to complete and submit the enclosed Foreign Activities Questionnaire, HHS 697 form. Some have found the questions and process confusing. Questions may arise concerning what is allowable and whether prior commitments made to foreign entities can be fulfilled while serving as an SGE for the NIH. This information sheet provides additional information, answers questions, clarifies the information required by the Foreign Activities Questionnaire, and provides names, phone numbers, and email addresses of people to contact for further clarification. We want to reassure you that we will work to resolve any problems, and usually you will be able to carry out all of your activities.

To whom and when does the Emoluments Clause apply?

- The Emoluments Clause applies to all Government employees, including you as an SGE
- The Emoluments Clause applies at all times during your appointment, not just the dates you are actually at the NIH.

What is the Emoluments Clause?

- The Emoluments Clause of the U.S. Constitution prohibits Government employees, including SGEs, from accepting any title, office, position, employment, emolument or gift from a foreign government or political subdivision of a foreign government, including certain public universities or commercial enterprises owned or operated by a foreign government, absent Congressional consent. Congressional consent to the acceptance of some gifts is found in the Foreign Gifts and Decorations Act.
- Emoluments include salary, honoraria, transportation, per diem allowances, household goods, shipment costs, and housing allowances.
- Exceptions include gifts less than \$305, or gifts that cover an educational scholarship, medical treatment, or expenses for travel taking place entirely outside the U.S. (including hotel and meal reimbursements in the foreign country, but not airfare for flights originating or terminating in the United States).

What foreign activities should I report under Question 1 of the Foreign Activities Questionnaire?

- Government employees, including SGEs, cannot accept any title, office, position, or employment, from a foreign government or political subdivision of a foreign government. You, therefore, need to report this type of activity for evaluation.
- A spouse or dependent child is permitted to hold a title or position and accept salary or compensation from a foreign entity. You are NOT required to report these activities on the HHS 697 form.

What is meant by foreign government or political subdivision of a foreign government? Question 2 of the Foreign Activities Questionnaire asks me to describe whether the foreign university is independent of the foreign government. How would I know this? How do I respond to this?

- A foreign government or political subdivision includes certain pubic universities, commercial enterprises owned or operated by a foreign government, and international organizations of which the U.S. is not a member.
- NIH ethics officials and advisory committee personnel will determine, with your assistance, if a foreign entity is independent of its government.
- The following criteria are considered when evaluating the status of foreign entities:
- o independence of management;
- o who makes personnel decisions;
- o are the members of the governing board appointed by the entity or by the Government;
- o to whom does the governing board report;
- o is the underlying source of funds a foreign government:
- o the nature of the proposed activity; and
- o the type of foreign entity/institution.

To find out if an organization is considered to be a foreign government or entity, please see the Contacts list at the end of this document.

Question 3 of the Foreign Activities Questionnaire asks me to describe tangible or intangible gifts that I anticipate receiving from foreign entities during my tenure as an SGE. What should I be reporting here?

- Gifts if valued at more than \$305: these can be accepted only for an educational scholarship, medical treatment, or expenses for travel taking place entirely outside the U.S.
- If, at anytime during your service, you have a question about whether you may accept a gift, please contact your Committee Management Officer or Deputy Ethics Counselor (see Contacts).

Are there any exceptions?

Because the Emoluments Clause is a part of the U.S. Constitution, waivers cannot be granted. However, NIH officials will work with you to determine whether certain activities may be permitted with those foreign entities otherwise considered part of a foreign government. Congressional consent affords certain exceptions to the rule, details of which can be found in the Foreign Gifts and Decorations Act. We have compiled the following list of guiding principles to help you determine which activities and gifts are exempt, and which are not.

- Tangible gifts valued at \$305 or less are exempt.
- Expenses for travel started and completed outside the U.S. are allowed.
- If the foreign activity is being done as part of your regular employment, and travel reimbursement is made to your employer rather than to you, then the activity will be permitted and travel beginning and ending in the U.S. can be reimbursed as long as the facts are consistent with your employer's historical "sponsored travel" practice.

If you have any questions about exceptions, please contact either your Committee Management Officer or Deputy Ethics Counselor (see Contacts).

As an SGE, what do I have to do with respect to the Emoluments Clause?

- You have to complete HHS-697 form, Foreign Activities Questionnaire, prior to your appointment, and yearly during your term of service.
- You must list all foreign institutions with which you have an activity. If you wish, you may obtain prior clearance for foreign activities from the Committee Management Officer or Deputy Ethics Counselor of the NIH Institute or Center with which you are working.
- If your Committee Management Officer or Deputy Ethics Counselor determines that a foreign institution has a relationship with its government, your options will be discussed with you.
- If, at any time during your service you have a question, please contact your Committee Management Officer or

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Deputy Ethics Counselor (see Contacts).

• You must not make representations to the U.S. Government on behalf of, or at the behest of, a foreign government, foreign political party or other foreign entity. If you are conducting such activities, they must be reported in Question 4 of the Foreign Activities Questionnaire.

If you have any questions with regard to this policy or information requested on the Foreign Activities Questionnaire, please contact:

Contacts:

IC Committee Management Officers - choose About Us and click on OFACP & CMO Staff Directory>

IC Deputy Ethics Counselors

References:

HHS-697 Foreign Activities Questionnaire

NIH Administrative Fact Sheet for Special Government Employees

Office of Federal Advisory Committee Policy (301) 496-2123

APPENDIX 6: Recusal List for SGE Advisory Committee Members

Sample Recusal List for SGE Advisory Committee Members

RECUSAL LIST FOR SGE ADVISORY COMMITTEE MEMBERS (for mm/dd/yyyy meeting)

NAME OF SGE MEMBER: _____Xxxxxxx, M.D.___

NAME OF ADVISORY COMMITTEE:

By law, you are prohibited from participating in Council/Committee discussions or action(s) relating to any specific party matter involving or affecting any of the following entities:

Name of Entity	Nature of Interest or Relationship	Expiration Date
Financial Interests		
Covered Relationships		

You are permitted to participate in general matters discussed at either open or closed sessions involving or affecting any of the above entities.

We have reviewed all other disclosures you have made, and have determined that such interests, holdings, and relationships do not pose a conflict of financial interest or an appearance of a conflict of interest.

APPENDIX 7: Sample 2635.502 Authorization for Appearances of Conflict of Interest

(For use in relation to a specific/identified/described matter or matters only)

DATE:

TO: [Name of Employee's Deputy Ethics Counselor or Designee]

FROM: [Name of Recommending Official]

SUBJECT: Authorization to Participate Under Section 2635.502 [Name of Individual]

I am writing on behalf of **[name of individual]**, a member of the **[name of advisory committee]**, to request that **[he/she]** be authorized to participate in all committee proceedings **[on/related]** to the **[identify agenda item]** matter pursuant to 5 C.F.R. § 2635.502(d). **[Name of SGE]** has a covered relationship with **[identify party to matter]** because **[identify basis of covered relationship]**, and there is a reasonable likelihood that the Committee's integrity, and hence that of the programs and operations of **[identify IC]**, will be questioned as a result of **[name of SGE]**'s participation in the matter. Nevertheless, I recommend that you authorize **[name of SGE]** to fully participate for the following reasons.

According to its charter, the [identify committee] is charged with [add description of committee functions and scientific focus]. [Name of SGE] is [describe the SGE's expertise in the field as basis of why the Government needs his/her services in relation to THIS matter]. Accordingly, [his/her] participation is crucial to the Committee's proceedings on this matter. Since [he/she] is only one member out of [number of appointed]

committee members] and shares responsibility for all recommendations made to federal officials equally with the others, and given the limited nature of **[his/her]** relationship with **[identify party to matter with whom SGE has a covered relationship]**, described above, the balance of views required by the Federal Advisory Committee Act will be preserved. Moreover, neither he nor the committee have decision-making or financing authority. **[Add any additional information that supports the SGE's participation despite the appearance problem.]**

Accordingly, I recommend that you authorize **[name of SGE]** to fully participate in the **[identify agenda item]** matter at the upcoming meeting.

DECISION:

_____ Authorization to participate granted based on my determination, made in accordance with section 2635.502(d), that "the need for the individual's services outweighs the concern that a reasonable person may question the integrity of the agency's programs and operations."

_____ Authorization to participate denied.

Deputy Ethics Counselor

Date

APPENDIX 8: Administrative Fact Sheet for Special Government Employees

An appointment on an NIH Advisory Council, Board of Scientific Counselors, or Program Advisory Committee requires NIH to appoint you as a Special Government Employee (SGE)¹. Federal laws and regulations require Government employees, which includes SGEs, to complete certain forms in relation to their Government service. These laws include the Ethics Reform Act of 1989, Immigration Reform and Control Act of 1986, Debt Collection Improvement Act of 1996, Civil Service Employment Law, and Federal Advisory Committee Act. Your appointment as an advisory committee member will be finalized once we receive all the completed forms listed below and the information that you provide is reviewed. So that we may finalize your appointment, please complete and return the following forms in the envelope provided:

- Executive Branch Confidential Financial Disclosure Report (OGE 450)
- Foreign Activities Questionnaire (HHS 697)
- Immigration and Naturalization Employment Eligibility Verification (I-9)
- Appointment Affidavit (SF 61) (Revised August 2002)
- Declaration for Federal Employment (OF 306) (Revised January 2001)
- Self-Identification of Handicap (SF 256)
- Direct Deposit (FMS Form 2231)
- Statement of Prior Federal Service (SF 144)
- Race and National Origin Identification (SF 181)
- Employee's Withholding Allowance Certificate (W-4)
- Employee's State Withholding Tax Form
- Record of Home Address (HHS-476)
- Consultant Verification Report

Detailed information for these forms is provided below. You are strongly encouraged to review this information before completing your forms. We also request that you pay close attention to information concerning the Executive Branch Confidential Financial Disclosure Report (OGE 450), and the Foreign Activities Questionnaire (HHS 697).

• Executive Branch Confidential Financial Disclosure Report (OGE 450)

- The Ethics Reform Act requires the collection of the information requested on this form. Your disclosure of this information is mandatory if you wish to be considered for membership.
- The information you disclose on this form will be used to determine whether there is an actual or apparent conflict of

^[1] A Special Government Employee is defined as an employee who is retained, designated, appointed, or employed to perform temporary duties either on a full-time or intermittent basis, with or without compensation, for a period not to exceed 130 days during any consecutive 365-day period. 18 U.S.C. 202.

Your appointment is contingent upon careful consideration of the information you provide. If for any reason you are not selected to serve on the committee, your completed OGE 450 report will be returned to you.

We are required by the Privacy Act to disclose the following information to you prior to your completion of the OGE 450 report:

interest between your employment and financial interests and your appointment as an NIH advisory committee member.

- Your information will remain confidential in the Committee Management Office and seen only by designated Government officials. The designated officials will review this information prior to each advisory committee meeting to help identify any potential conflict of interest situation which may arise. The information being solicited will be treated in a manner compliant with the Privacy Act. The information you provide will not be released to the public except by court order, request of the U.S. Congress, by the General Accounting Office as part of a Federal agency audit, or as otherwise provided under the Privacy Act.
- You will be required to update the information you provide on the OGE 450 report before each advisory committee meeting until the completion of your term. You will receive information when it is time for this update. The Ethics Reform Act provides that any individual who knowingly or willfully falsifies or fails to report the required information may be subject to criminal or administrative sanctions. You may be contacted for additional information if it is determined that the filed report does not provide enough information for a meaningful analysis of real or apparent conflicts of interest. A copy of the report, along with a form for verification of the information, will be sent to you before each meeting.

In addition to the instructions listed on the OGE 450 report and the supplemental instructions for reporting non-Federal research/training support, please note the following:

- Income includes foreign employment, summer and part-time employment, compensated membership on advisory boards of organizations, and consultant fees.
- Assets and Income include royalty agreements with, or stock ownership or options in, such organizations as, research institutions, drug companies, and companies that provide services to such organizations.
- When providing stock holdings, indicate the company's full name and the nature of the business when not obvious. If you own mutual funds concentrated in a particular geographic area or economic sector, indicate the area or industry in which the fund is primarily invested. If you own diversified and publicly traded mutual funds, they need not be listed on the form.
- If you or your spouse have control over assets from an employer-sponsored pension, you must list any underlying investment holdings; for all other employer-sponsored pension plans, you only need to indicate the name of the employer who sponsors the plan.

Foreign Activities Questionnaire and the Emoluments Clause of the U.S. Constitution

The Emoluments Clause of the United States Constitution applies to all U.S. Government employees, including all SGEs. The Emoluments Clause applies at all times during your appointment as an SGE and not just the periods of time during your actual duty on behalf of NIH. During your advisory committee appointment, you cannot be an employee of a foreign government entity. The Constitution prohibits you from receiving any present, emolument, office, or title of any kind from a foreign state. You also may not accept concurrent outside employment with a foreign government or a political subdivision of a foreign government, including certain public universities or commercial enterprises owned or operated by a foreign government. An emolument includes salary, honoraria, transportation, per diem allowances, household goods shipment costs, and housing allowances. Certain gifts and travel expenses outside the United States may be authorized by the Foreign Gifts and Decorations Act. You can be an employee of, or receive presents or emoluments from a non-government foreign entity or an international organization of which the U.S. is a member.

To help you determine if there is or could be a violation of the Emoluments Clause of the U.S. Constitution, the HHS Office of General Counsel, Ethics Division, has issued a mandatory form, HHS-697, *Foreign Activities Questionnaire*, which must be completed by all SGE advisory committee members. You are required to complete this **questionnaire prior to your appointment**, and yearly during your advisory committee service. You will receive the questionnaire prior to the first committee meeting of each calendar year to fulfill the yearly requirement.

Enclosed is an easy-to-read reference document, *Special Government Employees and Foreign Activities*, that we hope you will find helpful. If you need further information about the Emoluments Clause or if you have a conflict with this Statute, please contact the committee's Executive Secretary.

Consultant Verification Report

The purpose of the Consultant Verification Report is to verify information already part of the NIH computerized system of records. The data includes personal information, employment, research experience, and expertise used only by authorized NIH staff to identify potential/current consultants for NIH advisory committees and other peer review activities, and for statistical reporting.

• Employment Eligibility Verification (I-9) and Appointment Affidavit (SF 61)

These forms **must be notarized**. The NIH will allow a notary public to act as its agent for examination and verification of document(s) required to complete these forms. It is requested that you appear before a notary with the appropriate documentation and have the notary complete the forms according to the instructions.

The additional personnel forms listed on page one are also required to complete your appointment as an advisory committee member. These forms, however, do not have to be notarized. Please return the completed forms with the other forms in the enclosed envelope.

If you have any questions regarding these forms, please call **[Name of IC CMO or other appropriate official]** at **[area code + telephone number]** for assistance.

Other Important Information

• Standards of Ethical Conduct/Conflict of Interest

The Office of Government Ethics published Standards of Ethical Conduct for Employees of the Executive Branch which became effective on February 3, 1993, for all Government employees, including SGEs. This Final Rule established uniform standards of ethical conduct relating to many aspects of Federal Government employment, including conflicts of interest and the use of one's official position. These Standards apply to you in your SGE role and should be reviewed carefully. The Office of Government Ethics "Standards of Ethical Conduct for Employees of the Executive Branch" is available at the following website address:

http://ethics.od.nih.gov/LawRegs.htm

You are also required by Office of Government Ethics regulations to receive annual ethics training. Since on-site training is not always practical, this year's annual training requirement is being fulfilled by the distribution of the enclosed materials for your review:

- "Ethics Rules for Advisory Committee Members and Other Individuals Appointed as Special Government Employees (SGEs)"
- "OGE 2003 Conflict of Interest Prosecution Survey"
- "OGE Conflict of Interest and the Special Government Employee"

The criminal conflict of interest statutes preclude an SGE from participating as a Government employee in any particular matter in which, to his/her knowledge, they, their spouse, minor child, partner, or organization which they serve as officer, director, trustee, general partner, or employee has a financial interest. Whenever your participation in committee deliberations on a product, program, project or other particular matter would constitute a conflict of interest or create the appearance of one, it is incumbent upon you to so advise the Executive Secretary and abstain from any participation in discussion or action regarding that matter. When in doubt, you should seek a determination from the Executive Secretary of your committee.

• Reimbursement/Compensation

Members are compensated at the rate of \$200 per day for time spent at meetings and site visits. In addition, members are reimbursed for travel expenses and per diem incurred in connection with those activities. Members are compensated through the government payroll system. Social Security (except for non-citizens) and Federal Income taxes will be deducted, and a W-2 Wage and Tax Statement will be provided no later than January 31 each year. A separate payment will be processed for reimbursement of travel expenses and per diem. It is suggested that you retain a copy of the submitted record of travel expenses after each meeting. The daily per diem rate is determined by General Services Administration guidelines and is based on the city and state location of the meeting.

APPENDIX 9: Comparison Chart of Financial Interests vs. Covered Relationship - .pdf Format

<u>APPENDIX 10:</u> Sample Verification Form for Federal Employees (SF 278 or OGE 450 Filers) Serving on NIH Advisory Committees

VERIFICATION FORM FOR FEDERAL EMPLOYEES (SF 278 or OGE 450 FILERS) SERVING ON NIH ADVISORY COMMITTEES

I understand that my recusals/disqualifications and waivers currently in effect apply to matters that are the subject of the advisory committee on which I serve.

I agree to notify the Committee Management Officer of any changes in my financial interests since I last filed a financial disclosure report that may be affected by matters which are the subject of the advisory committee on which I serve.

Confirmed and acknowledged:

[Signature of Committee Member]

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[Date]

APPENDIX 11: Sample Letter for New Ex Officio Members

PRINT ON IC LETTERHEAD

[INSERT COMPLETE MAILING ADDRESS]

Dear____:

On behalf of the National Institutes of Health (NIH), I thank you for your willingness to represent [NAME OF AGENCY] as an ex officio member of the [NAME OF COMMITTEE].

To avoid any potential conflicts of interest related to your committee responsibilities, the Office of Government Ethics and the NIH requires all members and ex officio members of advisory committees to file financial disclosure forms prior to serving. In order to become a member, you must submit a copy of your OGE 450 "Confidential Financial Disclosure Report" filed with your agency. If you are a SF 278 "Public Financial Disclosure Report" filer, you must submit a copy of this form on file with your agency. Please forward a copy of your form in the enclosed envelope by [INSERT DATE]. Alternate ex officios whom you designate to attend the meeting in your absence must provide a copy of their SF 278 or OGE 450 form prior to attending the meeting.

I want to assure you that, if applicable, your OGE 450 form is covered by the Privacy Act and will be held strictly confidential by the National Institutes of Health and not released to the public. Only your "home" agency has the authority to release this information. To further safeguard your disclosure form, all SF 278s from other agencies are marked "Confidential-Not for Public Release." Information provided on the OGE 450 form is confidential and may not be released to the public except by court order, or by request of the U.S. Congress, by the General Accounting Office as part of a Federal agency audit, or as otherwise provided under the Privacy Act.

Again, I appreciate your willingness to represent your agency on the [NAME OF COMMITTEE] and know that the NIH will benefit from your counsel. If you have any questions concerning the conflict of interest requirements or your service on the Committee, please do not hesitate to contact me. I can be reached by telephone at (301) ______ or by e-mail at

Sincerely,

[Your signature]

Enclosures

APPENDIX 12: Sample COI Certification for Ex Officio Members and Alternates

Name of Committee: [INSERT NAME OF COMMITTEE]

Date of Meeting: [INSERT MEETING DATE]

This certifies that during the above described meeting, I absented myself and did not participate in discussions of any individual programs or projects in which I or to my knowledge my spouse, minor child, or partner has a financial interest, or are from an organization or institution where I am an employee, officer, director, trustee, general partner, or where I am negotiating for employment or otherwise have a financial interest or covered relationship.

In Committee discussions in which a consensus of recommendations were obtained on individual programs and projects, I did not participate in the discussion of any program or project from any institution fulfilling the criteria in the preceding paragraph.

Typed Name of Ex Officio Member or Alternate_____

Signature_____

Date_____

<u>APPENDIX 13:</u> Ethics Rules for Advisory Committee Members and Other Individuals Appointed as Special Government Employees (SGEs)

Introduction

This summary has been prepared primarily for individuals appointed to serve as "special Government employees" (SGEs) on Department of Health and Human Services (HHS) advisory committees or Presidential boards, councils, or commissions that are attached to HHS for purposes of administration. The information also will be useful to other SGEs without advisory committee responsibilities, such as "experts or consultants" or "personal services contractors."

New appointees, especially those that provide temporary, intermittent services only a few days a year, are often surprised by, or even resentful of, the complexity of the rules governing Federal employees. The ethics rules do not appear to many people to be logical, intuitive, or even fair. Ignoring these rules, however, can result in serious consequences or embarrassment, both personally and for the Department. Criminal conflict of interest violations are "strict liability" offenses, and even an inadvertent, "technical" violation will require the initiation of an Inspector General investigation and possible referral to the Department of Justice. Moreover, the entire matter in which a violator participates may be considered so compromised that the Department may have to nullify, cancel, or retract any agency action that is perceived as tainted by the conflict. Therefore, if you have questions on any of the topics covered in this guidance, you should consult with the Designated Federal Official responsible for your committee or the Deputy Ethics Counselor assigned to your operating or staff division.

Definition of a Special Government Employee (SGE)

A "special Government employee" is an officer or employee in the executive branch of the Federal Government who is appointed to perform temporary duties, with or without compensation, for a period not to exceed 130 days during any period of 365 consecutive days. 18 U.S.C. § 202(a). This status is important because the ethics rules for SGEs are somewhat <u>less</u> restrictive than the rules for other Federal employees and officials. Some members of advisory committees are appointed for a multi-year term. During each year of their term of appointment, committee members generally will not be expected to perform work for HHS in excess of 130 days during any period of 365 consecutive days. Thus, most committee members will be considered "SGEs."

In addition, individuals who provide advice as an "expert or consultant," or render assistance under a "personal services contract" for a period not expected to exceed 130 days do so as the functional equivalent of an employee and thus are treated as SGEs for ethics purposes. Only "true" independent contractors are excluded from the definition. Although several factors are evaluated to determine independent contractor status, this category, for the most part, comprises individuals who produce a defined "end product" or "deliverable" without detailed supervision by a Federal employee.

Financial Disclosure Reporting Requirements

HHS advisory committee members appointed as SGEs are required under the Ethics in Government Act, as amended by the Ethics Reform Act of 1989, and 5 C.F.R. Part 2634, to file a financial disclosure report when first appointed and annually thereafter on the anniversary date of their appointment. Committee members also may be required to update the information on the report before each meeting throughout their term of appointment. (Certain committee members are permitted to utilize an alternative reporting system, e.g., FDA Form 3410, that focuses solely on each filer's assets and associational interests that are directly implicated by the subjects on the meeting agenda.) The information reported is used to determine the matters for which a committee member must be disqualified under the criminal financial conflict of interest statute, 18 U.S.C. § 208(a), and the matters for which a committee member may be granted a waiver under 18 U.S.C. § 208(b).

Complete reporting is essential to protect the committee member from inadvertently violating any of the criminal conflict of interest statutes, and to assure the public that the advice provided by an HHS advisory committee is free from any real, or perceived, conflicts of interest. The information reported by committee members is confidential and may not be released except under the limited circumstances described in the Privacy Act notice provided with the report or by order of a Federal court. (SGEs who serve more than 60 days in any period of 365 consecutive days and who are compensated at certain pay levels may be required to file a publicly available financial disclosure report).

Criminal Conflict of Interest Statutes

The following criminal conflict of interest statutes apply to SGEs:

18 U.S.C. § 201. Section 201, commonly known as the "bribery and illegal gratuities" statute, prohibits Federal employees, including SGEs, from seeking, accepting, or agreeing to receive anything of value in return for being influenced in the performance of an official act.

18 U.S.C. § 203. Section 203 prohibits an SGE from receiving compensation for <u>representational services</u> rendered by the employee or another person before HHS or another Federal agency or other specified entity (such as a court or commission) in any <u>particular matter involving a specific party</u> (i) in which the SGE has participated personally and substantially as a Government employee, or (ii) which is pending in the Government agency in which the SGE is serving if the SGE has served for more than 60 days during the immediately preceding 365 days.

A <u>particular matter involving specific parties</u> is a matter that is focused upon the interests of identified persons in a specific proceeding or an isolatable transaction or related set of transactions. Examples include, but are not limited to, reviews of grant proposals or contract applications, or similar funding decisions; recommendations or approvals of scientific studies, projects, clinical trials, new drug applications; and other actions that involve deliberation, decision, or action affecting the legal rights of identified parties.

In contrast, a <u>particular matter of general applicability</u> is a matter that is focused on the interests of a discrete and identifiable class of persons or entities, but does not involve specific parties. Examples include recommendations or consideration of legislative proposals, regulatory initiatives, or policy development that affect an industry, group of manufacturers, or health care providers.

Pay close attention to which type of particular matter is involved in your assignment because the ethics rules may differ depending upon whether a "specific party matter" or a "general policy matter" is involved. The terms "matter" or "particular matter," without more description, are deemed to encompass both types.

<u>Representational services</u> include communications (written or oral) and appearances made on behalf of someone else, generally with the intent to influence or persuade the Government. An inquiry as to the status of a pending matter is not necessarily a representation, although depending upon the context of the inquiry, it could give rise to the appearance of a prohibited representation.

To avoid appearance problems, during the period in which a committee is in session, committee members are advised not to contact Department staff concerning any matters pending before the agency, or as to which the agency has an interest. Such matters would include, for example, applications for Federal funding, progress reports regarding Cooperative Research and Development Agreements (CRADAs) or clinical trials, and pending drug investigations or applications.

18 U.S.C. § 205. Section 205 prohibits an SGE from <u>representing</u> a party, with or without compensation, before HHS or another Federal agency or other specified entity (such as a court or commission) in any <u>particular matter involving a specific party</u> in which the United States is a party or has a direct and substantial interest: (i) that the SGE participated in personally and substantially as a Government employee; or (ii) which is pending in the agency in which the SGE is serving, if the SGE has served for more than 60 days during the immediately preceding 365 days.

18 U.S.C. § 207. Section 207, the "post-employment" statute, imposes a lifetime ban on a former SGE from representing another person or entity to HHS or another Federal agency or other specified entity (such as a court or commission) in any <u>particular matter involving a specific party</u> in which the former SGE participated personally and substantially while serving in the Government. In addition, for two years after terminating Federal employment, an SGE may not make such representational communications to the Government regarding specific party matters that were pending under his or her official responsibility during the last year of Government service. Moreover, "senior employees," those paid at an annual rate equivalent to level ES-5 in the Senior Executive Service, are subject to a one-year "cooling-off" period which precludes any contacts with their former agency on any matter for which official action is sought, even if the former employee had no involvement with the matter while in Government service. For SGEs, this one-year "cooling-off" period does not apply if the SGE served less than 60 days in the one-year period prior to termination of senior employee status.

18 U.S.C. § 208. Section 208(a), the main <u>conflict of interest</u> statute, prohibits an SGE from participating personally and substantially in <u>any particular matter</u> that could affect the financial interests of the SGE, the SGE's spouse, minor child, general partner, an organization in which the SGE serves as an officer, director, trustee, general partner, or employee, or an organization with which the SGE is negotiating or with which the SGE has an arrangement for prospective employment.

Under this statute, for example, an SGE would be prohibited from reviewing a grant application submitted by a researcher from the same university in which the SGE is employed, or a contract proposal from an association for which the SGE serves as a member of the board of directors. In these instances, the SGE would be required to recuse from participation in the reviews.

Section 208 might also prohibit the SGE from participating in setting standards for grantees or contractors in general, to the extent that the SGE's university (or any organization with which the SGE is affiliated as an officer or board member) would be affected by those standards. (Under this scenario, however, a waiver could be issued to permit the SGE to participate in such general policy matters. Also, a regulatory waiver might apply to this situation. See discussion below.)

A <u>waiver</u> for advisory committee members may be granted under 18 U.S.C. § 208(b)(3). Section 208(b)(3) authorizes issuance of a waiver to an SGE who serves on a committee subject to the Federal Advisory Committee Act if the official responsible for the individual's appointment certifies in writing that the need for the individual's services outweighs the potential for a conflict of interest created by the particular financial interest involved. The waiver granted is considered a "general" waiver, in that it allows participation in matters that affect all institutions, or types of institutions, similarly.

Even with a general waiver, however, SGEs must disqualify themselves from participation in all matters that specifically and uniquely affect their financial interests. The Designated Federal Official responsible for a committee will explain the procedures for disqualification. SGEs who do not serve on advisory committees are subject to more exacting waiver requirements in 18 U.S.C. § 208(b)(1), and a Deputy Ethics Counselor should be consulted.

In addition, under regulations issued by the Office of Government Ethics, a regulatory (i.e., automatic) waiver of the disqualification requirement of 18 U.S.C. § 208 is available under certain circumstances, including instances involving the following classes of financial interests:

- interests held in broadly diversified investment funds;
- publicly traded securities of \$15,000 or less;
- publicly traded securities of \$25,000 or less if the matter is a general policy matter and the total value of all investments in the affected industry sector is no more than \$50,000; and
- employment in one campus of a multi-campus state university if the matter affects only another campus and the employee does not have multi-campus responsibilities.

In addition, there is an automatic exemption which allows SGEs serving on Federal advisory committees to participate in matters of general applicability where the otherwise disqualifying financial interest arises solely from the committee member's non-Federal employment or prospective employment, provided that the matter will not have a special or distinct effect on the employee or employer other than as part of a class. This exemption is unavailable if the employee (or those persons whose interests are imputed to the employee) owns stock, stock options, or has some other financial interest in the employer other than his or her employment interest.

18 U.S.C. § 219. Section 219 prohibits an SGE from acting as an "agent of a foreign principal" as defined under the Foreign Agents Registration Act (FARA) or a "lobbyist" on behalf of a foreign entity that is required to register under the Lobbying Disclosure Act of 1995 (LDA).

The ban on participating in foreign agent activities covered by FARA prohibits representation of foreign governments or foreign political parties before the United States Government, as well as a number of other activities conducted within the United States on behalf of such entities: (1) political activities; (2) public relations counseling; (3) publicity agent activities; (4) information services; (5) political consulting; and (6) solicitation or disbursement of contributions, loans, money, or other things of value; where such services are rendered with the intent to influence the American public or the Government, with reference to formulating the domestic or foreign policies of the United States, or with reference to the political or public interests, policies, or relations of a government of a foreign country or a foreign political party.

There are certain FARA exceptions related to trade or commerce, legal representation, humanitarian fundraising, and religious, scholastic, or scientific pursuits. The head of an agency may authorize the employment of an agent for a foreign entity as a special Government employee upon a certification that such action is in the national interest. The LDA ban prohibits certain lobbying of covered legislative and executive branch officials on behalf of foreign corporations, associations, or other organizations.

Standards of Ethical Conduct

In addition to criminal statutes, the conduct of SGEs is governed by a series of ethics rules that apply 24 hours per day and even on days during which the SGE provides no Federal services. The following are some of the major Standards of Ethical Conduct regulations (5 C.F.R. Part 2635) that pertain to HHS SGE advisory committee members during the term of their appointment:

1. Teaching, Speaking, and Writing in a Personal Capacity (i.e., Other Than as a Government Employee)

Generally, during their term of appointment, committee members may continue to receive fees, honoraria, and other compensation for teaching, speaking and writing undertaken in their personal or non-Governmental capacities. However, there are some limitations:

(A) An SGE is prohibited from receiving compensation for teaching, speaking, and writing that "relates to the employee's official duties." 5 C.F.R. § 2635.807. The "relatedness" test is met for an SGE if:

(1) the activity is undertaken as an official Government duty;

(2) the circumstances indicate that the invitation to engage in the activity was extended to the SGE primarily because of the employee's position in the Government rather than the employee's expertise in the particular subject matter;

 $\overline{(3)}$ the invitation to engage in the activity or the offer of compensation for the activity was extended to the employee, directly or indirectly, by a person who has interests that may be affected substantially by the performance or nonperformance of the employee's official duties; or

(4) the information conveyed through the activity draws substantially on ideas or official data that are confidential or not publicly-available.

(B) Additionally, if a committee member serves for 60 days or less during a one-year period, the SGE may <u>not</u> accept compensation for teaching, speaking, and writing if the subject matter of the teaching, speaking, or writing concerns a <u>particular matter involving specific parties</u> in which the SGE participated or is participating personally and substantially as a Government employee.

For example, an AIDS researcher has been appointed to a four-year term as a member of an advisory committee established for the purpose of surveying and recommending modification of procedures that deter the development of treatments for HIV infection and HIV-related diseases. The committee member is not expected to serve more than 60 days each year during her four-year term of appointment.

The committee member may accept compensation for an article or speech about the deterrent effect of certain procedures required for clinical investigations and trial designs even though such issues are being discussed by the advisory committee. Clinical procedures in general are <u>not</u> a particular matter involving specific parties. The committee member could <u>not</u> accept compensation for an article or speech which recounts committee deliberations that took place in a closed meeting, or which relies upon other, non-public information. In addition, the committee member could <u>not</u> accept compensation for an article or speech about specific collaborations in the HIV drug development process which were discussed by the committee, since the collaborations are considered a <u>particular matter involving</u> specific parties.

(C) If a committee member serves for **more** than 60 days, the SGE is additionally prohibited from receiving compensation for teaching, speaking, and writing if the subject of the activity deals in significant part with any matter to which the SGE is presently assigned or was assigned during the previous one-year period.

EXCEPTIONS:

1. This rule does not preclude a committee member from receiving compensation for teaching, speaking, or writing on a subject within the committee member's discipline or inherent area of expertise based on the SGE's educational background or experience. The outside activity must not be about or distinctly related to the work the SGE is providing to the Government.

2. These restrictions also do <u>not</u> apply to teaching a course requiring multiple presentations that is part of the regularly established curriculum of an institution of higher education, an elementary or secondary school, or a program of education or training sponsored and funded by the Federal, State, or local government.

II. Gifts

Any gift given to a committee member because of the member's service on an HHS advisory committee would raise concerns. The Designated Federal Official responsible for the committee should be consulted should this situation arise. Gifts given to an SGE because of the SGE's position or achievements in the private (non-Government) sector generally are not problematic

III. Charitable Fundraising

A committee member may engage in charitable fundraising in a personal capacity as long as the committee member does not personally solicit funds or other support from any person or entity known to the committee member to be a person or entity whose interests may be substantially affected by the performance or nonperformance of the committee member's Federal duties. 5 C.F.R. § 2635.808. If specific questions concerning particular fundraising events or activities should arise, the Designated Federal Official responsible for the committee should be consulted.

IV. Expert Witness

A committee member cannot serve as an expert witness, in a proceeding before a United States court or agency in which the United States is a party or has a direct and substantial interest, except on behalf of the United States, <u>if</u> the committee member participated, while a Federal employee, in the particular proceeding, unless authorized by the HHS Designated Agency Ethics Official (DAEO), who can be reached at (202) 690-7258.

In addition, a committee member who was appointed by the President, serves on a commission established by statute, or has served or is expected to serve for more than 60 days in a period of 365 consecutive days, cannot serve, other than on behalf of the United States, as an expert witness, with or without compensation, in any proceeding before a United States court or agency in which the committee member's employing agency is a party or has a direct and substantial interest unless authorized by the DAEO. 5 C.F.R. § 2635.805.

V. Impartiality

Although committee members are prohibited under 18 U.S.C. § 208(a) from participating in matters in which they have a financial interest, there may be other circumstances in which a committee member's participation in a particular

matter involving specific parties would raise a question regarding the member's impartiality in the matter. For example, a committee member asked to review a grant application submitted by the SGE's mentor, or someone with whom the SGE has a close personal or professional relationship, would raise a concern about the committee member's impartiality in the review. In such circumstances, the committee member should discuss the relationship with the Designated Federal Official responsible for the committee and a determination will be made as to whether the member should be disqualified from participation in the specific party matter, or should be granted an "authorization" to permit the member to participate in the matter. 5 C.F.R § 2635.502.

VI. Misuse of Position

Committee members are subject to a number of prohibitions intended to address the use, or appearance of use, of "public office for private gain." 5 C.F.R. Part 2635, Subpart G. These prohibitions include:

(A) Using their HHS titles or referring to their Government positions for their own private gain, the private gain of friends, relatives, or anyone with whom they are affiliated in a non-Governmental capacity (including nonprofit organizations which they serve as officers, members, employees, or in any other business relationship), or for the endorsement of any product, service, or enterprise;

(B) Using their HHS titles or Government positions to coerce or induce another person to provide any benefit to themselves or another person;

(C) Using non-public Government information in a financial transaction to further their private interests or those of another, or disclosing confidential or non-public information without authorization; or

(D) Using Government property for unauthorized purposes.

Employment by, or Gifts from, Foreign Governments

The Constitution prohibits a committee member's employment by a foreign government, including political subdivisions of a foreign government. For SGEs, this provision has particular relevance to positions with foreign universities that are government-operated, as opposed to private institutions. United States Constitution, art. I § 9, cl. 8. There are also statutory provisions restricting acceptance of gifts from foreign governments. 5 U.S.C. § 7342. Committee members should consult with the Designated Federal Official responsible for their committee for details about these restrictions. Employment or consultation with a foreign entity for the purpose of providing foreign agent representation or lobbying is barred by a criminal statute; see the discussion above concerning 18 U.S.C. § 219. All SGEs are required to complete HHS Form 697, Foreign Activities Questionnaire, for the purpose of determining whether a committee member's foreign connections are incompatible with Federal service.

Lobbying Activities

In their official capacities or as a group, committee members are prohibited from engaging in any activity which directly or indirectly encourages or directs any person or organization to lobby one or more members of Congress. 18 U.S.C. § 1913. When authorized, committee members may appear before any individual or group for the purpose of informing or educating the public about a particular policy or legislative proposal. Committee members may also communicate to Members of Congress <u>at the request of any Representative or Senator</u>. Communications to Members of Congress initiated by committee members, in their official capacity as members of the committee, should be coordinated through the Office of the Assistant Secretary for Legislation.

As private citizens, committee members may express their personal views (but not the views of the committee as a whole or the opinions of HHS) to anyone. In doing so, committee members may state their affiliation with the committee, may factually state the committee's official position on the matter (to the extent that non-public information is not used), but may <u>not</u> take new positions and represent those views as the committee's position on the matter. Moreover, in expressing their private views, as with all other personal (non-Governmental) activities, committee members are not permitted to use Government computers, copiers, telephones, letterhead, staff resources, or other appropriated funds. All personal activities must occur "off duty time."

Committee members are prohibited in their personal capacities from making representations on behalf of others, to the Government, on <u>particular matters involving specific parties</u> in which they were involved as Federal employees. (See discussion above under 18 U.S.C. §§ 203 & 205.)

Political Activities

The Hatch Act (5 U.S.C. §§ 7321-7326) prescribes the restrictions on certain political activities of Federal employees (see the explanatory chart on the following page). Unlike the criminal conflict of interest statutes and the ethics rules which are fully applicable to an SGE throughout the SGE's entire term of appointment, the Hatch Act restrictions apply only during the period of any day in which the SGE actually is performing government business. For example, if an SGE attends an advisory committee meeting from 8:00 am - 1:00 pm, the SGE could attend a political fund raiser at 3:00 p.m. and even solicit political contributions from the attendees.

A series of criminal political statutes (18 U.S.C. §§ 595, 600-603, 606-607, 610) applies to SGEs even on non-duty hours. These sections, which focus on patronage crimes and election offenses, prohibit coercive

"political shakedowns," intimidation regarding political activities, campaign fundraising on Federal property, and the use of public office or authority for the purpose of affecting the outcome of an election.

HATCH ACT POLITICAL ACTIVITY RESTRICTIONS

Permissible Activities	Prohibited Activities (while on duty)
 * May be candidates for public office in nonpartisan elections * May register and vote as they choose. * May assist in voter registration drives. * May express opinions about candidates and issues. * May contribute money to political organizations. * May attend political fund raising functions. * May attend and be active at political rallies and meetings. * May join and be an active member of a political party or club. * May sign nominating petitions. * May campaign for or against referendum questions, constitutional amendments, municipal ordinances. * May campaign for or against candidates in partisan elections. * May distribute campaign literature in partisan elections. * May hold office in political clubs or parties (except Treasurer). 	 * May not use their official authority to interfere with an election. * May not collect political contributions, unless both individuals are members of the same Federal labor organization and the one solicited is not a subordinate employee. * May not knowingly solicit or discourage the political activity of any person who has business before the agency. * May not engage in political activity while on duty. * May not engage in political activity in any Government office. * May not engage in political activity while wearing an official uniform. * May not engage in political activity while using a Government vehicle. * May not solicit political contributions from the general public. * May not actively participate as a candidate for public office in a partisan election.

APPENDIX 13a: Notice for Members Affiliated with Certain Firms

Please be advised that you are prohibited from receiving compensation (including partnership distribution, bonus, or other share of the profits) as a result of your firm's representation of a specific client on a particular matter that is the subject of the Committee's meetings. (18 U.S.C. Sections 203 and 205.) For further information, please consult the Deputy Ethics Counselor.

<u>APPENDIX 14:</u> Tracking Form, "Clearance Process to Identify and Resolve Potential Conflicts of Interest," for SGE Advisory Committee Members - <u>.pdf format</u>

<u>APPENDIX 15:</u> Chart: Conflict of Interest/Ethics Procedures and Requirements for Special Government Employees and Peer Reviewers - <u>.pdf format</u>

APPENDIX 16: Conflict of Interest: Frequently Asked Questions

Question 1: Can a Special Government Employee (SGE) advisory committee member accept compensation, i.e., honorarium and travel expenses, for outside speaking at a conference?

Answer: The Standards of Ethical Conduct (5 C.F.R. Part 2635), Section I - Teaching, Speaking and Writing in a Personal Capacity (Other than as a Government Employee) states: An SGE is prohibited from receiving compensation for teaching, speaking, and writing that "relates to the employee's official duties." 5 C.F.R. 2635.807. The exception is that an SGE may accept compensation for speaking on subjects within their "discipline or inherent area of expertise" based on their educational background or experience. They cannot accept compensation for the outside activity if the speaking concerns matters they participate in due to their position on the Federal advisory committee. The outside speaking cannot relate to the work the SGE is providing to the Government.

Question 2: Can a Special Government Employee (SGE) advisory committee member accept reimbursement for

honoraria, travel, or hotel expenses when invited to speak at a conference sponsored totally, or in part, by a government funded foreign university?

Answer: The Emoluments Clause of the United States Constitution prohibits anyone who holds an Office of Profit or Trust in the Government from accepting a position with a foreign state, whether compensated or uncompensated, or from accepting any compensation or other items of value, including salary, honoraria, and travel expenses from a foreign state, except as authorized by Congress. The Department of Justice, Office of Legal Counsel (OLC) has advised that members of Federal advisory committees are deemed to hold an Office of Profit or Trust within the meaning of the Emoluments Clause unless they serve strictly in a representative capacity. OLC has indicated that the policy behind the Emoluments Clause, requiring the undivided loyalty of individuals occupying positions of trust under our government, has as much force with respect to part-time employees as it does with respect to full-time employees. The OLC opinions make clear that the Emoluments Clause applies at all times during the committee member's appointment, and not just on the days when actually performing Federal services. For purposes of the Emoluments Clause, a foreign state includes international organizations where the United States is NOT a member. In addition, a foreign public university is presumed to be part of the foreign state, unless the university is independent of the foreign government with respect to decisions regarding the terms and conditions of faculty appointment. In all cases, the committee member will bear the burden of obtaining and providing to the agency information sufficient to make such determinations. A non-inclusive list of foreign states that are considered independent of their foreign government may be found at:

http://ethics.od.nih.gov/Topics/foreign.htm.

Question 3: Can a SGE nominee be appointed and serve on an advisory committee without submitting an OGE 450 confidential financial disclosure form?

Answer: No. SGE advisory committee members are required under the Ethics in Government Act, as amended by the Ethics Reform Act of 1989, and 5 C.F.R. Part 2634, to file a financial disclosure report. Appointment to the committee is contingent upon careful consideration of the information provided in relation to the member's committee responsibilities. Complete reporting is essential to protect the committee member from inadvertently violating any of the criminal conflict of interest statutes, and to assure the public that the advice provided by an advisory committee is free from any real, or perceived, conflicts of interest. The information reported on the OGE 450 is confidential and may not be released to the public except by court order, by request of the U.S. Congress, by the General Accounting Office as part of a Federal agency audit, or as otherwise provided under the Privacy Act.

Question 4: Are all Federal advisory committee members required to file the OGE 450 confidential disclosure report?

Answer: No. The Ethics in Government Act, as amended by the Ethics Reform Act of 1989, and 5 C.F.R. Part 2634, require only SGE advisory committee members to file an OGE 450, Confidential Financial Disclosure Form. Members of scientific and technical peer review groups are not appointed as SGEs and, therefore, are not subject to these filing requirements. NIH scientific and technical peer reviewers acknowledge real and potential conflicts by signing pre- and post-review conflict of interest certifications.

Question 5: Is a Veterans Administration employee serving on a Council in conflict if they are reviewing an application from VA? Are there any exceptions for VA employees serving on Councils?

Answer: There is a regulatory exemption under 18 U.S.C. § 208 that provides that Federal employees are not in conflict when they participate in funding application reviews from their employing agencies. On the other hand, employees are required under 5 C.F.R. 2635.502, to avoid situations where a reasonable person may question their impartiality. An individual from VA may give the appearance of being in conflict if they were reviewing a VA application from another VA institution. Therefore, this Standard would prohibit the member from participating in the review unless an authorization was granted.

Question 6: Must a Council member who is employed by Howard Hughes Medical Institute (HHMI) recuse him/herself when a grant application from another HHMI investigator is being reviewed?

Answer: Yes, an HHMI Council member would have to leave the room when a grant application from another HHMI investigator is being reviewed. The Council member would also have to absent or recuse him/herself from matters involving the institution where he is affiliated.

However, HHMI peer reviewers serving on IRGs may review grant applications from other HHMI investigators. This policy change for the initial peer review phase was effective November 6, 1995, as recommended by EPMC's HHMI Committee and approved by HHMI officials, IC Directors, and the NIH Director.

Question 7: May an SGE advisory committee member from Harvard University review a grant application from Harvard Medical School?

Answer: The SGE member may participate in the review of the grant application if he or she: 1) does not hold a joint appointment with the Medical School, 2) does not have affiliate-wide responsibilities, and 3) has a waiver to review the grant.

Question 8: Does a Council member absent him/herself from the portion of a meeting that he/she is in conflict with, i.e., an application from his/her institution? Does he/she have to leave the entire segment of the grant reviews that are included in an en bloc?

Answer: During the review of an individual application or a block of applications where a Council member has a conflict in relation to the individual application, or any application in a block being considered, the Council member must recuse/disqualify him/herself from any discussion or deliberation on the individual application or the block under consideration. In addition, the conflicted Council member may not vote on the individual application, and his/her vote on a block of applications would not apply to any application in the block with which he/she has a real or apparent conflict (as reported on his recusal list).

Question 9: As a private citizen, may an SGE committee member lobby a member of Congress?

Answer: As private citizens, committee members may express their personal views (but not the views of the committee as a whole) to anyone. All personal activities must occur off duty time. Committee members are not permitted to use Government computers, copiers, telephones, letterhead, staff resources or other appropriated funds for personal activities. In their official capacities or as a group, committee members are prohibited from engaging in any activity that directly or indirectly encourages or directs any person or organization to lobby one or more members of Congress. 18 U.S.C. section 1913.

Question 10: Are SGE advisory committee members restricted in participating in political activities?

Answer: The Hatch Act (5 U.S.C. sections 7321-7328) prescribes restrictions on certain political activities of Federal employees. However, the Hatch Act restrictions apply only during the period of any day when the SGE is actually performing Government business. For example, if an SGE attends an advisory committee meeting from 8:00 a.m. to 1:00 p.m., the SGE could attend a political fund-raiser at 3:00 p.m. and even solicit political contributions from the attendees. A listing of permissible activities and prohibited activities (while on duty) may be found at the end of *Ethics Rules for Advisory Committee Members and Other Individuals Appointed as Special Government Employees*, on the web at http://www1.od.nih.gov/cmo/ethics/ethics01.pdf .

Question 11: May an SGE advisory committee member review a grant application submitted by 1) the SGE's domestic partner, or 2) an organization that paid the member an honorarium in the past year?

Answer: No to both. Committee members are prohibited under 18 U.S.C. section 208(a) from participating in matters where they have a financial interest. A committee member's participation in a particular matter involving specific parties (in this case, the domestic partner and the organization) would raise a question of the member's impartiality, and could give the appearance of a conflict. However, if the Institute/Center Deputy Ethics Counselor determines that the need for the SGE's services outweighs the concern that a person may question the integrity of the agency's programs and operations, an authorization may be granted, allowing the SGE to participate in the matter. 5 C.F.R. Part 2635 section 502.

Question 12: Do ex officio advisory committee members have to verify their financial interests prior to each meeting?

Answer: Yes. The IC CMO will send the member a Verification of Financial Interests form prior to each meeting for updating. The IC CMO will review the updated information in relation to the ex officio's committee responsibilities and meeting agenda. If a conflict is identified, the ex officio member's home agency must prepare a waiver, or the member must recuse him/herself from participating in the particular matter(s) with which he/she has the conflict(s). Only the home agency has authority to grant waivers to ex officio members.

Question 13: Does a conflict of interest exist for a member who holds several positions, e.g., Professor, Consultant, Board of Directors member, Chair of Board, but does not accept compensation for service on the advisory committee?

Answer: Yes. The fact that a member holds a position with these entities could create a conflict, even if the member is not paid for his committee service.

Question 14: How should patents be reported on conflict of interest forms?

Answer: A patent that is not marketable and is not producing any income need not be reported. However, where no royalties are being received but an individual has an agreement with a patent holder (university, company, etc.) pursuant to which royalties will be paid should the technology be licensed, sold, etc., that agreement needs to be reported in Part IV of the OGE 450 report.

A patent that is either marketable with a value exceeding \$1,000 OR generating royalties exceeding \$200 in the time period covered by the OGE 450, needs to be reported in Parts I and IV. A patent may pose a conflict of interest if the committee will act on a matter affecting that patent. A waiver to act on general matters which may affect similarly situated patent holders may be granted to SGE members if it is deemed that the need for the member's services outweighs the potential for a conflict of interest created by the financial interest. In the absence of a waiver, the member would be disqualified from participating in the matter and would leave the room. Non-SGE members must recuse themselves from the review, regardless of the level of financial involvement, if they are unable to provide objective advice.

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