NIH Policy Manual

1810-1 - Procedures for Avoiding Conflict of Interest for Special Government and other Federal Employees Serving as Advisory Committee Members

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Transmittal Notice

1. **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 serving as members of NIH advisory committees.
2. **Filing Instructions:**

   Remove: NIH Manual 1810-1 dated 12/31/05.
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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) and other federal employees appointed, selected, or designated to serve as members of NIH advisory committees subject to the Federal Advisory Committee Act (FACA). Since federal employees may serve as regular or *ex officio* members of National Advisory Councils and Boards, Program Advisory Committees, and Boards of Scientific Counselors, procedures relevant to these members are also included in this chapter (see Section E.7. "NIH Committee Management Handbook" for a glossary of terms).

This chapter describes procedures designed to ensure: (1) the appropriate collection, review, and evaluation of financial disclosure report forms for prospective and current SGE advisory committee members and federal employees serving as *ex officio* or regular members on advisory committees; (2) Institutes and Centers employ a standardized process of review of

financial disclosure reports; (3) waivers and authorizations are executed, where appropriate; (4) appropriate collection, review, and evaluation of the Foreign Activities Questionnaire (HHS Form 697) for prospective and current SGE advisory committee members; (5) SGE advisory committee members receive annual ethics training; and (6) compliance with federal records and Privacy Act requirements.

This chapter does not address conflict of interest policies, procedures, and forms that have been developed for peer reviewers, working group participants who are not members of the federal advisory committee, and others who are not SGEs and other federal employees who are members of NIH federal advisory committees.

B. Background

The Standards of Ethical Conduct for Employees of the Executive Branch, 5 C.F.R. Part 2635, became effective February 3, 1993, for all government employees, including SGE advisory committee members. These individuals 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 C.F.R. Part 2634. Additionally, federal employees and SGE advisory committee members must comply with restrictions imposed by Title 18 of the U.S. Code, by the Emoluments Clause of the U. S. Constitution (Article I, section 9, Clause 8), and by the Foreign Gifts and Decorations Act (5 U.S.C. § 7342).

Additional information about the laws and regulations and their application to SGE members of federal advisory committee members, documents referenced in this chapter, forms, templates, sample letters, and other guidance can be found at the NIH Office of Federal Advisory Committee Policy web site: http://ofacp.od.nih.gov/.

C. Policy

NIH's policy is to avoid financial conflicts of interest, or the appearance of such conflicts, in the operation and work of federal advisory committees managed by the NIH; to maintain adequate records regarding financial and organizational interests of such committee members; and to safeguard the confidentiality of these records.

D. Coverage

This chapter covers SGEs and other federal employees who are appointed, selected or designated to serve as members of the National Advisory Councils and Boards, Program Advisory Committees, and Boards of Scientific Counselors of the NIH, as well as committees managed by NIH to advise the President of the United States or the Secretary of the Department of Health and Human Services (HHS). 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. Federal employees may be selected or designated as regular or *ex officio* members of these committees.

Members of initial/integrated scientific and technical peer review groups and special emphasis panels are not appointed as SGEs and are **not** covered by this chapter. The Office of Extramural Research (OER) establishes policies and procedures regarding conflict of interest for members of these committees.

E. References

1. Executive Order 12674 (April 12, 1989), as modified by Executive Order 12731 (October 17, 1990), "Principles of Ethical Conduct for Government Officers and Employees."
2. 18 U.S.C. § 208. Crimes and Criminal Procedure. Sec. 208. Acts Affecting a Personal Financial Interest.
3. 5 U.S.C., App. Federal Advisory Committee Act.
4. 5 C.F.R. Part 2635, "Standards of Ethical Conduct for Employees of the Executive Branch."
5. 5 C.F.R. Part 2634, "Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture."
6. Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services, 5 C.F.R. Parts 5501 and 5502.
7. NIH Committee Management Handbook
8. NIH Delegations of Authority, General Administration #9B, "Grant Conflict of Interest Waivers for IC Directors and Advisory Committee Members" (appointed by the Director, NIH, or Secretary, HHS).
9. NIH Manual 1743: "Keeping and Destroying Records", Introductory Note and Parts 1100-G-6 and 1100-G-8-b.
10. NIH Manual 2400-3: "Executive Branch Confidential Financial Disclosure Reporting System, OGE Form 450" (revised 4/1/2011).
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.
14. HHS Form 697: "Foreign Activities Questionnaire"
15. OGE Form 450: "Confidential Financial Disclosure Report"
16. OGE Form 278: "Public Financial Disclosure Report"

F. Responsibilities

1. **Director, Office of Federal Advisory Committee Policy (OFACP), Office of the Director (OD)/NIH**

    a. Function as liaison between the Office of the Secretary; the Office of the General Counsel, Ethics Division (OGC/E); the Office of the General Counsel, Public Health Division (OGC/PHD); the NIH Ethics Office (NEO); the NIH Office of Human Resources; and the Institutes and Centers of NIH concerning the Federal Advisory Committee Act and appointment and conflict of interest matters

relating to NIH advisory committee members covered by this chapter.

b. Furnish policy and guidance to NIH officials for collecting, reviewing, and handling conflict of interest information for NIH advisory committee members covered by this chapter.
c. Establish necessary controls and procedures to ensure compliance with applicable laws, regulations and policies, and submission of required documents and reports.

2. **Institutes and Centers (IC) Committee Management Officers (hereafter variously IC CMO or CMO depending on context)**

Consistent with Section G. of this chapter, CMOs:

a. Ensure that prospective SGE advisory committee members receive letters of invitation, personnel and ethics forms, a copy of an Administrative Fact Sheet, which provides instructions for completing the forms, a link to the Standards of Ethical Conduct for Employees of the Executive Branch, and other specified ethics materials referenced in the Administrative Fact Sheet.
b. Notify the appropriate IC Deputy Ethics Counselor (DEC) of a newly selected or designated NIH employee member.
c. Obtain initial financial disclosure reports and periodic updates from current and prospective SGE advisory committee members, initial and annual Foreign Activity Questionnaires from current and prospective SGE advisory committee members, periodic notices from IC DECs regarding NIH employees serving on advisory committees managed by NIH, and copies of annual financial disclosure reports filed by individuals employed by other federal agencies and serving on advisory committees managed by NIH.
d. Review financial disclosure, verification, and foreign activity forms of prospective and current SGE advisory committee members, and the financial disclosure forms of individuals employed by other federal agencies serving on advisory committees managed by NIH, to ensure forms are fully and properly completed in accordance with the Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture regulations, 5 C.F.R. Part 2634, and Supplemental Instructions approved by the Office of Government Ethics (OGE) for NIH SGE advisory committee members, and obtain additional information when necessary.
e. In coordination with the Designated Federal Officer (hereafter Executive Secretary) and IC DEC, and based upon the actual work of committee (including review of funding applications or proposals, strategic planning, and intramural research laboratory reviews), identify potential conflicts of financial interest and impartiality concerns.
f. As appropriate, draft waivers, recusal lists, and authorizations for SGE advisory committee members and, consistent with IC procedures for its use, prepare the *Tracking Form: Clearance Process to Identify and Resolve Potential Conflicts of Interest for Federal Advisory Committee Members*. In coordination with IC DEC, obtain OGC/E clearance of draft waiver according to OGC/E requirements and instructions.

g. Obtain recusal, waiver, and authorization information for NIH employees serving as regular or *ex officio* committee members from employees' DECs. Work with IC DEC, committee member employed by another federal agency, and the member's ethics official to obtain recusal, waiver, and authorization information.
h. Identify potential emolument and foreign gift issues reported on members' HHS 697 forms. Consult with the IC DEC and OGC/E when necessary for determinations and regarding resolution.
i. Periodically obtain verification from non-NIH federal employees serving as regular and *ex officio* members, including *ex officio* alternates and delegates, that they understand that their current recusals and waivers remain in effect and of their agreement to report any new or additional need to recuse as a result of changes in their financial interests that may be affected by matters before the committee.
j. Together with the Executive Secretary and the IC DEC, ensure that new regular and *ex officio* members who are federal employees (but not NIH employees) are informed of the NIH requirement that they provide a copy of their financial disclosure form before attending a committee meeting, and periodically thereafter upon request. In the case of *ex officio*members, this requirement also applies to any alternates. If *ex officio* members or their alternates do not comply in a timely manner, the CMO alerts the committee's Executive Secretary to obtain, in connection with a single meeting or committee-related activity, a one-time certification of no conflicts of interest.
k. Ensure that all SGEs receive required annual ethics training and maintain documentation that training material was sent, that the website address for reviewing the electronic training material was provided, and/or that in-person training was held.
l. 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 NIH Manual 1743, "Keeping and Destroying Records," Introductory Note and Part 1100-G-6.)
m. Provide copies of all waivers/addenda issued to SGE members to OGC/E.

3. **Designated Federal Officers (Executive Secretaries) of NIH Advisory Committees**

a. Acquire a working knowledge of pertinent statutes, regulations, policies, and procedures regarding conflict of interest, impartiality requirements, financial disclosure, and foreign activities, and periodically attend training sessions on evaluation of conflict of interest situations.
b. Together with the IC CMO and DEC, ensure that SGEs are fully aware of conflict of interest and financial disclosure requirements and, where appropriate, resolve any conflicts before service.
c. Together with the IC CMO and DEC, ensure that all non-NIH federal members, regular and *ex officio*, and *ex officio* alternates, are fully aware of conflict of interest and financial disclosure requirements and understand any recusal obligations.

d. Review financial disclosure forms submitted upon initial appointment, selection, or designation of a committee member and periodic updates thereafter. In coordination with the IC CMO and DEC, and based upon actual work of committee (including review of funding applications or proposals, strategic planning, and intramural research laboratory reviews), identify potential conflicts of financial interests and impartiality concerns, and recommend waiver or authorization where appropriate and otherwise consistent with agency policy, signing all documents as required.
e. Review Foreign Activities Questionnaire (HHS 697 form) from prospective SGE advisory committee members prior to appointment, and then once yearly during their term of service.
f. Ensure that the procedures used to avoid conflicts of interest during meetings and other committee activities are consistent with this issuance, and document procedural compliance.

4. **Program Staff, Review Staff, and Grants Management Staff (Program Staff)**

a. Provide guidance, in their respective areas of authority, as appropriate, to assist advisory committee members in avoiding participation in real or apparent conflict of interest situations.
b. In their respective areas of authority, remain alert to advisory committee members' possible conflict of interest situations, and advise and assist CMO, Executive Secretary, IC DEC and other officials with committee-related duties.

5. **Institute and Center Deputy Ethics Counselors, and NIH Ethics Office (IC DECs)**

a. Within their respective ICs, implement the government ethics program consistent with their delegations of authority. The NIH Ethics Office functions as the IC Ethics Office for OD-managed advisory committees. DECs in the ICs and the NIH Ethics Office serve as primary points of contact on ethics matters related to their IC employees and their IC's advisory committees (although the NIH DEC is the IC DEC for OD-managed advisory committees). DECs may delegate authorities and functions as provided in their delegation of authority.
b. Manage financial disclosure reporting systems and:

    1. Review and certify financial disclosure reports filed by SGEs serving on federal advisory committees managed by their IC, ensuring that reports are fully and properly completed as required under the Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture regulations, 5 C.F.R. Part 2634, and Supplemental Instructions approved by the Office of Government Ethics for NIH SGE advisory committee members;
    2. Collect, review, and certify financial disclosure reports of NIH employees within the scope of their ethics program jurisdiction who serve as regular or *ex officio* members of federal advisory committees; and

3. Review financial disclosure reports of individuals employed by other federal agencies who serve as regular or *ex officio* members, including *ex officio alternates and delegates*, of federal advisory committees managed by their IC.

c. Provide advice and guidance to the IC CMO regarding the application of conflict of interest and impartiality requirements and technical completion of financial disclosure forms.
d. In coordination with the IC CMO and the Executive Secretary of the advisory committee, identify conflicting financial interests and assess impartiality concerns for SGE and NIH and non-NIH federal employee advisory committee members, and identify available remedies.
e. Remedy potential conflicts of interest and impartiality concerns through:

1. The issuance of waivers or authorizations, and recusal lists for SGE advisory committee members where appropriate and consistent with legal standards.
2. Notification to NIH employees serving on advisory committees managed by NIH and Committee Management staff of relevant recusal obligations and any applicable waivers or authorizations; and
3. Notification to non-NIH federal employee member of relevant recusal obligations following coordination with non-NIH federal employee member, the employing agency and, as needed, OGC/E, regarding the possibility or existence of a waiver or authorization.

NOTES:

(1) IC DECs have delegated authority to grant waivers to SGE advisory committee members after OGC/E review and determination that the document is factually accurate and legally sufficient. This IC DEC signature authority cannot be redelegated.

(2) IC DECs may grant an authorization under the impartiality standard to NIH FTEs or SGEs within the scope of their ethics program jurisdiction.

(3) Only the NIH Director can issue a waiver to an NIH FTE.

f. Provide advice and guidance to the IC CMO regarding the application of the Emoluments Clause of the U.S. Constitution and the Foreign Gifts and Decorations Act.

6. **Advisory Committee Members**

a. SGEs:

1. Promptly complete OGE 450 and HHS 697 forms as requested. Return completed forms to IC CMO, along with other required appointment

documents.
2. Upon receipt, promptly review OGE 450 and *Verification Log*, and complete next section of *Verification Log*, identifying any changes in financial interests. Return updated*Verification Log* to CMO.
3. Comply with recusal obligations.

b. NIH Employees:

1. Promptly complete OGE 450 and/or cooperate with DEC requests for additional information or explanation that may be needed to clear participation in committee matters or identify scope of recusal obligation.
2. Comply with recusal obligation.

c. Federal employees of other agencies serving as regular and *ex officio* members, and *ex officio* alternates:

1. Promptly provide a copy of most recent financial disclosure form filed with employing agency upon receipt of invitation and/or notification of designation to serve and periodically thereafter upon request.
2. Promptly sign and submit certification regarding existing recusal obligations and understanding of obligation to recuse based upon changes in financial interests since last OGE 278 or OGE 450 filed.
3. Comply with recusal obligations.

7. **NIH Ethics Counsel, Office of the General Counsel, Ethics Division (OGC/E)**

a. Function as the NIH liaison to the Department of Justice (DOJ), the Office of Government Ethics (OGE), and the HHS Designated Agency Ethics Official (DAEO).
b. Provide guidance on the implementation of policies and procedures set forth in this issuance to ensure consistency with DAEO, DOJ, OGE, and other government-wide legal requirements, interpretation, and policy expectations.
c. Provide advice and guidance on conflicts of interest, impartiality concerns, financial disclosure, and foreign activities issues. When appropriate, provide detailed guidance to CMOs, IC DECs and/or committee Executive Secretaries on new and/or changing requirements, policies, and procedures.
d. Review OGE 278 financial disclosure forms filed by the Director, NIH, the Director, NCI, and the Principal Deputy Director, NIH, who serves as the NIH DEC, for any potential conflict of interest due to committee responsibilities.
e. Review and transmit a copy of each signed waiver issued under the authority of 18 U.S.C. § 208 to the OGE.

G. Implementation

1. **Overview**

In order to avoid conflicts of interest and/or the appearance of conflict in the work of federal advisory committees managed by the NIH, CMOs in consultation with IC DECs, Executive Secretaries, and other appropriate staff facilitate and coordinate compliance with all applicable government ethics requirements.

Government-wide rules of ethical conduct prohibit federal employees, including SGEs, from participating in particular matters in which they have a conflict of financial interest or covered relationship. The financial interests and professional and business relationships of federal advisory committee members are reviewed and analyzed prior to their committee appointments and periodically throughout their term of service.

Specifically, in light of the variety of activities advisory committee members undertake in connection with their committee service, including the review of funding applications, strategic planning, and intramural research laboratory reviews, the update and review of the financial interests and covered relationships of members occurs:

a. Two times per calendar year – for committees that meet two or fewer times in each calendar year; and
b. Three times per calendar year – for committees that meet three or more times in each calendar year.

2. **Procedures for Clearing Prospective SGE Advisory Committee Members**

    a. Upon approval of nomination, the CMO sends a letter of invitation or acknowledgment.
    b. Upon receipt of the potential SGE member's assent to serve, the CMO send the required appointment forms, including the OGE 450 and HHS 697 forms and the Administrative Fact Sheet, with additional and supplemental instructions and guidance prescribed by OFACP, to the prospective SGE advisory committee member.
    NOTE: At the discretion of the White House Ethics Counsel, alternate procedures and additional vetting requirements may apply in relation to prospective SGE members who may be appointed by the President.
    c. Immediately upon return receipt from the prospective SGE, the IC CMO and DEC reviews the OGE 450 form for completeness, returning an incomplete form to the prospective SGE or contacting the prospective SGE to obtain additional required information.
    NOTES:

        1. *New SGE members will be formally appointed only after clearance of the OGE 450 form and completion of the human resources appointment process.*
        2. *In the event the next regular update mailing date arrives before the prospective member's original OGE 450 clearance process is complete AND the original OGE 450 was submitted more than: (a) four (4) months prior in the case of a committee that meets 3 or more times per year; or (b)*

six (6) months prior in the case of a committee that meets two or fewer times per year, the prospective member must be asked to update as part of the ongoing initial clearance process

d. The CMO, in consultation with the DEC, Program Staff, and Executive Secretary, as needed, reviews the completed OGE 450 form and other available information and disclosures, including the prospective SGE's curriculum vitae and HHS 697 form, to identify the prospective SGE's financial interests and covered relationships and determine, in light of the work of the committee, whether any appear to pose any potential conflict of financial interest, would cause a reasonable person to question the individual's impartiality, or otherwise result in a violation of any applicable ethical conduct requirement.
e. Based on the legal determination obtained from OGC/E and OGC/PHD and posted on the OFACP website, the CMO determines whether the prospective member will be subject to the Emoluments Clause by virtue of appointment:

    1. For prospective members who will be **subject** to the Emoluments Clause, the CMO identifies any title(s), office(s) emolument(s) or gift(s) reported by the prospective member and, if necessary, consults with the Executive Secretary and IC DEC or OGC/E regarding appropriate resolution; or
    2. For prospective members **not subject** to the Emoluments Clause, the CMO identifies any gratuitous gift(s) reported by the prospective member (excluding positions or durational relationships and honoraria or other payment or reimbursement intended to compensate for service rendered or to be rendered) and, if necessary, consults with the Executive Secretary and IC DEC or OGC/E regarding appropriate resolution.

f. Based upon consultation with the Executive Secretary and/or Program Staff, as needed, CMO records the prospective member's financial interests in and covered relationships with entities that may be parties to or affected by matters that will come before the committee on a recusal list.
g. Based upon consultation with the Executive Secretary and/or Program Staff, as needed, the CMO drafts, if needed, a conflict of interest waiver request, listing all relevant financial interests, except employment relationships. If appropriate based upon such consultations and guidance materials posted on the OFACP web site, the CMO prepares a draft authorization to permit the SGE to participate in a specific party matter involving an entity with which the SGE has a covered relationship.
h. Regarding waivers:

    1. if a waiver is **not** required, the CMO, consistent with IC procedures for its use, prepares the Tracking Form: Clearance Process to Identify and Resolve Potential Conflicts of Interest for Federal Advisory Committee Members (COI Tracking Form) and sends the OGE 450 form, recusal list, and any draft authorization documents, signed by the Executive Secretary, to the IC DEC for review and signature; or

2. if a waiver **is** required, the CMO sends the OGE 450 form, recusal list, and draft waiver (and any authorization) documents, **without** signature of the Executive Secretary, to the IC DEC for review. Once IC DEC concludes the OGE 450 form is technically complete, and that all relevant financial interests and covered relationships have been identified and proposed for appropriate resolution, all documents are forwarded to OGC/E consistent with OGC/E requirements and instructions. Once the proposed waiver is determined by OGC/E to be factually accurate and legally sufficient, the CMO, consistent with IC procedures for its use, prepares the Tracking Form: Clearance Process to Identify and Resolve Potential Conflicts of Interest for Federal Advisory Committee Members, and returns the package to the Executive Secretary and IC DEC for review and signature.

i. The IC DEC returns all original documents to the CMO to file and maintain in the member's file with (but not attached to) the SGE advisory committee member's OGE 450 form.
j. The CMO, in consultation with the Executive Secretary, ensures that the prospective SGE is advised to recuse from matters that pose an actual or apparent conflict of financial interest and regarding other relevant remedial actions taken or that will be necessary.
k. The CMO transmits a copy of the final recusal list and signed waiver to the prospective SGE and the Executive Secretary, and provides a second copy of both documents to the SGE and the Executive Secretary at the time of the next in-person meeting.
l. The CMO advises his/her HR contact that the prospective member has been cleared for appointment.
m. Upon request from OGC/E, the CMO sends a copy of each signed waiver to OGC/E per the instructions provided.

NOTES:
(1) A new OGE 450 form is not required for members being extended or reappointed to the same committee (e.g., extended pending a new member appointment, reappointments to Chair; reappointments from a partial term to a full term) provided the total service to date does not exceed six years (calculated from the date of the Title 5 appointment) and there is no break in service. A new OGE 450 form will be required if/once an extended or reappointed member has served for more than six years.
(2) Waivers and the recusal list apply and relate to all particular matters scheduled for discussion at open and closed sessions of advisory committee meetings and any committee work an SGE may undertake between meetings, including activities undertaken as part of a working group. Particular matters may be general or specific, and involve deliberation, decision and/or action. Examples include: grants, contracts, licenses, patents, lawsuits, and policy-making. ***Members must adhere to recusal obligations at all times of service.***
(3) An authorization applies to a specified matter involving parties and may be issued, if appropriate, at any time during the SGE's term. If an authorization is granted, it constitutes a limited exception from the recusal requirement that otherwise remains in

effect.
(4) The 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.

3. **Procedures for Clearing Current SGE Advisory Committee Members Annually:**

    a. The CMO sends the HHS 697 form to members, with additional instructions and guidance prescribed by OFACP, on an annual basis. This may or may not coincide with a request to members to verify their financial interests.
    b. The CMO reviews and determines based upon the legal determination obtained from OGC/E and OGC/PHD and posted on the OFACP website whether a member is subject to Emoluments Clause by virtue of appointment:

        1. For a member subject to the Emoluments Clause, the CMO identifies any title(s), office(s), emolument(s) or gift(s) reported and, if necessary, consults with the Executive Secretary and IC DEC or OGC/E regarding appropriate resolution; or
        2. For members not subject to the Emoluments Clause, the CMO identifies any gratuitous gift(s) reported (excluding positions or durational relationships and honoraria or other payment or reimbursement intended to compensate for service rendered or to be rendered) and, if necessary, consults with the Executive Secretary and IC DEC or OGC/E regarding appropriate resolution.

    Periodically:

    c. The CMO sends a copy of the member's original OGE 450, the member's most recent Member Conflict of Interest Verification Log (Verification Log) and the member's most recent recusal list to each SGE advisory committee member in accordance with the established schedule.
    d. Upon receipt of the package, the SGE members review their financial interests, activities, and other relationships and provide updated information on the Verification Log reflecting any changes that have occurred since their last report. The SGE signs the Verification Log and returns it to the CMO.
    If the updated Verification Log is not returned by the SGE member within 30 calendar days after the package is sent out, the SGE advisory committee member may not participate in any committee or committee-related activities.
    e. Immediately upon return receipt, the CMO, in consultation with the DEC and Executive Secretary, as needed, reviews the Verification Log and determines whether there are any new financial interests or covered relationships that pose any potential conflict of financial interest or that would cause a reasonable person to question the individual's impartiality, or otherwise result in a violation of any applicable ethical conduct requirement.
    NOTES:
    (1) In the event issues or questions about a member's last Verification Log

remain open when the next regular update mailing date arrives, the member must be asked to update again as part of the ongoing process and the member may not participate in any committee or committee-related activities until the open question(s) is resolved.

(2) Because committee members may participate in committee-related activities at various times throughout their terms, all members will be instructed to update their Verification Log on each mailing cycle regardless of expected attendance at any meeting.

f. The CMO updates the recusal list to reflect any new or additional financial interests in or covered relationships with entities that may be parties to or affected by matters that will come before the committee, and to remove any financial interests no longer held and covered relationships in relation to which the recusal obligation has expired.

g. Based upon consultation with Executive Secretary or Program Staff, as needed, the CMO drafts, if needed, a conflict of interest waiver listing all previously listed financial interests the member still has, and new relevant financial interests, except employment relationships. If appropriate based upon such consultations and guidance materials posted on the OFACP web site, the CMO prepares a draft authorization to permit the SGE to participate in a specific party matter involving an entity with which the SGE has a covered relationship.

h. Regarding waivers:

    1. if a new or updated waiver is **not** required, the CMO, consistent with IC procedures for its use, prepares the Tracking Form: Clearance Process to Identify and Resolve Potential Conflicts of Interest for Federal Advisory Committee Members, and sends the OGE 450 form, Verification Log, previously issued waiver, updated recusal list, and any draft authorization documents, signed by the Executive Secretary, to the IC DEC for review and signature as needed; or
    2. if a new or updated waiver strong>is required, the CMO sends the OGE 450 form, recusal list, and draft waiver (and any authorization) documents, **without** signature of the Executive Secretary, to the IC DEC for review. Once the IC DEC concludes the OGE 450 and Verification Log form are technically complete, and that all relevant financial interests and covered relationships have been identified and proposed for appropriate resolution, all documents are forwarded to OGC/E consistent with OGC/E requirements and instructions. Once the proposed waiver is determined by OGC/E to be factually accurate and legally sufficient, the CMO, consistent with IC procedures for its use, prepares the Tracking Form: Clearance Process to Identify and Resolve Potential Conflicts of Interest for Federal Advisory Committee Members, and returns the package to the Executive Secretary and IC DEC for execution.

i. The DEC returns all original documents to the CMO to file and maintain in member's file with (but not attached to) the SGE's OGE 450 and Verification Log.

j. The CMO, in consultation with the Executive Secretary, ensures that the SGE is advised to recuse from matters that pose an actual or apparent conflict and regarding other remedial actions taken or that will be necessary.
k. The CMO transmits a copy of the updated recusal list and any current waiver to the SGE and Executive Secretary once they are completed and provides a second copy of both documents to the SGE and Executive Secretary at the time of the next in-person meeting.
l. Upon request from OGC/E, the CMO sends a copy of each signed waiver to OGC/E per the instructions provided.
NOTES:
(1) In order to develop a consistent practice, all appointed members will receive notice to update their Verification Log regardless of how recently the initial or last clearance was completed.
(2) Waivers and the recusal lists apply and relate to all particular matters scheduled for discussion at open and closed sessions of advisory committee meetings and any committee work an SGE may undertake between meetings, including activities undertaken as part of a working group. Particular matters may be general or specific, and involve deliberation, decision and/or action. Examples include: grants, contracts, licenses, patents, lawsuits, and policy-making. Members must adhere to recusal obligations at all times of service.
(3) An authorization applies to a specified matter involving parties and may be issued, if appropriate, at any time during the SGE's term. If an authorization is granted, it constitutes a limited exception from the recusal requirement that otherwise remains in effect.

4. **Procedures for Clearing NIH Employees Serving as Regular or *Ex officio* Members of NIH Advisory Committees**

a. Upon the selection or designation of an NIH employee to serve on an advisory committee managed by NIH, the CMO notifies the employee's DEC (i.e. NEO for OD employees and Top 5 employees within ICs; the DEC of employing IC for all others, and sends a copy of the committee charter to the employee's DEC.

NOTES:
(1) In the case of the Secretary, the Director, NIH, the Director, NCI, and the NIH DEC, due to additional requirements and limitations imposed in connection with their appointments, OGC/E will inform OFACP in the event any of them have recusal obligations. OFACP will, in turn, provide the information to CMOs as needed.

(2) All NIH employees serving as members of NIH Advisory Committees covered by this Manual Chapter are required to file a financial disclosure report (OGE 278 or OGE 450). If an employee selected or designated to be a member is not already a financial disclosure report filer, the employee's DEC must immediately notify the employee that s/he must file an OGE 450 report within 30 calendar days, and annually thereafter for so long as the employee serves on the

committee or otherwise has duties necessitating confidential financial disclosure. Once the new entrant report has been reviewed and certified consistent with financial disclosure requirements, the employee's DEC and the CMO handling the committee proceed with the following steps prior to the employee's service on the committee.

b. Upon selection or designation, and thereafter when requested by the CMO based upon the update schedule established for the committee, the employee's DEC reviews the most recent financial disclosure report and other ethics information (seeking confirmation from the employee, as needed) to identify whether, in light of the work of the committee, any financial interests or covered relationships pose any potential conflict of financial interest, would cause a reasonable person to question the individual's impartiality, or otherwise result in a violation of any applicable ethical conduct requirement.
c. The employee's DEC provides written notice (via email) to the employee and the CMO of all relevant recusal obligations, taking into account the full scope of 18 U.S.C. § 208 as it applies to particular matters of general applicability and specific party matters, 5 C.F.R. § 2635.502, and any existing waivers that would apply to the employee's duties on the committee.
d. The employee's DEC maintains the original financial disclosure report and other ethics files; the CMO retains a copy of the notice from the employee's DEC regarding recusals and waivers.

5. **Procedures for Clearing non-NIH Federal Employees Serving as Regular or *Ex officio* Members of NIH Advisory Committees**

a. Upon selection or designation to serve on an advisory committee managed by NIH, the CMO sends a letter to the non-NIH federal employee informing him or her that he or she must submit a copy of his or her most recent financial disclosure form (OGE 278 or OGE 450) that is on file with his or her home agency **before** serving on the federal advisory committee, and annually thereafter (in April for an OGE 450 filer, and in July for an OGE 278 filer (see *note (3)*, below)). **This requirement also applies to alternate/delegate *ex officio*members serving in the member's absence.** Except as provided below, a new federal, *ex officio (or alternate)* or regular, member may not attend a meeting unless and until this requirement is met.

NOTES:

(1) NIH does not have authority to request that an employee from another agency complete an OGE 450 form if he or she does not have a financial disclosure report on file. In the event an individual does not have a form on file, the CMO or IC DEC may contact the ex officio member's home agency ethics official to request that the member complete an OGE 450 form. Contact information for ethics officials at each agency can be found at: http://www.oge.gov/Program-Management/Program-Management-Resources/Ethics-Community/DAEO-List/.

(2) OGE 278 forms received from other agencies or their employees must be marked "Confidential – Not for Public Release," and maintained like OGE 450 reports. OGE 278 reports may be requested from the individual's employing agency.

(3) Federal employees may request up to an additional 90 days within which to file their annual financial disclosure reports. Accordingly, while CMOs will request the OGE 450 reports filed by federal employee members in April of each year and OGE 278 reports filed by federal employee members in July of each year, OGE 450 filers will be viewed as complying with this policy provided their report is submitted on or before August 15, and OGE 278 filers will be viewed as complying with this policy provided their report is submitted on or before November 15.

(4) A non-NIH federal employee member appointed to serve on an NIH advisory committee based solely on their expertise, not their federal position (i.e. as a regular member), does not have the option of identifying an alternate to serve in their place either for the term of the appointment or individual meetings. If that non-NIH federal member is unable to accept the position on the committee, then NIH will appoint another individual to serve for that term. The Executive Secretary may invite an ad hoc member to replace a non-NIH federal member who cannot attend a meeting when particular expertise is needed.

*(5) A non-NIH federal member designated to serve on an NIH advisory committee based on their federal position identified in legislation and/or the committee's charter (e.g. and ex officio member) may identify a permanent alternate. If the permanent alternate cannot attend an individual meeting, a temporary alternate may be permitted to attend a meeting**provided** that the financial disclosure requirements of paragraph a. are met.*

b. The CMO, in consultation with the IC DEC and Executive Secretary, as needed, reviews the non-NIH federal employee, regular or *ex officio (or alternate),* member's OGE 278 or OGE 450 form in relation to committee responsibilities and meeting agenda to determine whether any reported financial interests or covered relationships pose any potential conflict of financial interest, would cause a reasonable person to question the individual's impartiality, or otherwise result in a violation of any applicable ethical conduct requirement, taking into account the full scope of 18 U.S.C. § 208 as it applies to particular matters of general applicability and specific party matters, and 5 C.F.R. § 2635.502. The home agency will not have ready access to this information and would therefore be less-equipped than NIH officials to identify potential conflicts of interest.
c. Consistent with IC procedures for its use, the CMO includes the non-NIH federal employee, regular or ex officio (or alternate), member on the next COI Tracking Form prepared, attaching the form for transmission to and review by the Executive Secretary and IC DEC.

d. The CMO, Executive Secretary, and/or IC DEC confer with the federal member and/or the non-NIH federal employee, regular or ex officio (or alternate), member's home agency ethics official regarding any identified sources of conflict or impartiality concerns. Only the employing agency has authority to grant waivers or authorizations to its employees. If a conflict or other problem is identified based upon review of the federal member's OGE 278 or OGE 450, the home agency must issue the waiver or authorization. In the absence of such a waiver or authorization, the federal member must be recused from participating in all particular matter(s), including matters of general applicability and those involving specific parties with which he or she has the conflict(s). The CMO may share a sample format of a waiver containing appropriate language regarding the function and objective of the committee (e.g. the duties of the members) and the need for the individual's service (i.e. statutory requirement or expertise).
e. The CMO, in consultation with the Executive Secretary and/or IC DEC ensures that the non-NIH federal, regular or ex officio (or alternate), member is advised to recuse from all particular matters with which he or she has a conflict, taking into account any relevant waiver or authorization issued by the home agency, and signs the Verification Form for Non-NIH Employees prescribed by OFACP before attending a committee meeting or otherwise participating in committee-related activities, and annually thereafter.
f. Except as provided here, a non-NIH federal employee, regular or ex officio (or alternate), member may not attend a meeting or otherwise participate in committee-related activities unless or until he or she complies with the financial disclosure requirements of paragraph a., review is completed, and the individual has signed the Verification Form for Non-NIH Federal Employees. If an individual does not submit his or her financial disclosure form within 60 days of receipt of the invitation letter, or, subsequently, by the annual deadline (see note (3), above), and the individual's expertise is deemed by the Executive Secretary to be critical for upcoming committee activities, the individual may be permitted to attend one meeting or participate in a particular committee-related activity provided that he or she must certify, by signing the Conflict of Interest Certification form, immediately following the meeting or other committee-related activity that he or she did not participate in any matters in which he or she may have been in conflict. Use of this certification should be unique and infrequent, and can only be used once by any individual.

   Following use of this form, the individual must submit a copy of his or her financial disclosure form within 30 calendar days. If the member or alternate does not submit the form within the 30 day period, the Executive Secretary, in consultation with OFACP and the IC Director, must seek another member.
g. The CMO retains copies of any relevant waivers or authorizations, and notices regarding recusal obligations, with (but not attached to) the OGE 278 or OGE 450 form of each non-NIH federal, regular or ex officio (or alternate), member. Regarding confidentiality, see note (2), above.

H. Annual Ethics Training Requirement

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), receive annual ethics training.

The OGC/E determines the content of annual training programs and approves any requested changes.

CMOs are required to maintain documentation that training material was sent and the website addresses for reviewing electronic training materials was provided. Additional, in-person training is encouraged for the SGE advisory committee member(s), but does not supplant the annual training requirements provided by OGC/E.

I. 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.

J. 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 NIH Manual 1743, "Keeping and Destroying Records," Item 1100-G, "Committee Management," Introductory Note and Part 1100-G-6, "Confidential Financial Disclosure Report (OGE 450), and Waivers," Item 2300-730-7, "Financial Disclosure Reports," Item 1100-G-21, "Financial documents," Item 1100-G-8-b, "Individual Committee Meeting Records," as follows:

IC Committee Management Offices are responsible for retaining original copies of all OGE 450 forms, Verification Logs, and related ethics agreements for 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. All other records and documents related to government ethics matters, including HHS 697 forms, must be retained for six years or until they are superseded or obsolete, whichever is later, 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" OGE 278 forms received from other agencies must be marked "Confidential-Not for Public Release," and maintained like the OGE 450 forms. The OGE 278 forms are publicly available from the members' home agencies.

All other records including lists of members present during votes, and other supporting papers pertinent to the meetings of the committee are maintained and then destroyed when 10 years old, except as needed in an ongoing investigation and until investigation is completed.

NIH e-mail 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 and must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Liaison 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. Back-up files are subject to the same requests as the original messages.

K. Internal Controls

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 SGEs 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 or *ex officio* members on NIH federal advisory committees.

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

   OFACP, in consultation with IC DECs, and OGC/E.

   Through this manual issuance, the OFACP in the Office of the Director, NIH, is accountable for ensuring that CMOs have implemented appropriate internal controls.
2. **Frequency of Review:**

   OFACP staff conducts ongoing as well as biennial reviews of CMO files, as described below. Annual ethics training, coordinated by OFACP, is also provided to the CMOs. In addition, the Office of Government Ethics or the HHS Office of the General Counsel, Ethics Division, 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 OFACP 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 OFACP during monthly meetings with IC CMOs, and through continuous individual discussions between OFACP staff and IC CMOs. The OFACP staff also maintains 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:**

   OFACP reviewers send their reports to the Director, OFACP, and when appropriate, the IC DECs and OGC/E, NIH, indicating that controls are in place and working well, or include any internal control issues that should be brought to the attention of the report recipients.