

OFACP Policy:

HHS Membership Policy for Federal Advisory Committee Members and Procedures for Requesting a Waiver

September 2015

Background: On February 8, 1995, the Assistant Secretary for Health delegated to the Director, National Institutes of Health (NIH), authority to approve membership waivers under the Department of Health and Human Services (HHS) policy regarding excessive and multiple committee service. This policy applies to committee membership for individuals appointed to all NIH Federal Advisory Committees. Committee appointments include individuals serving as regular (standing) members and chairs as well as those designated to serve at individual Initial/Integrated Review Group and their Subcommittees (Study Section) meetings (Temporary members) and Special Emphasis Panels (SEP members). The authority to approve waivers for peer review committee membership was re-delegated to the Deputy Director, NIH on August 23, 2011. This policy is being re-issued to modify procedures for requesting these waivers and update procedures for membership waiver requests for appointments made by the President and the Secretary, HHS. In addition, the re-issued policy incorporates additional guidance that had been provided previously in a separate addendum.

HHS Policy on Excessive and Multiple Committee Memberships

It is HHS policy to avoid excessive individual service on advisory committees and multiple committee memberships, including designation to serve at individual meetings as a Temporary or SEP member. This policy **does not apply to individuals serving as an ad hoc attendee at a council meeting or a mail reviewer**. Only sections (c) and (d) below apply to individuals serving as Temporary and SEP members. Specifically, HHS policy provides that a Federal Advisory Committee member will not:

- (a) Serve continuously as a member of any single advisory committee for more than four years [Note: NIH committees that have appointment periods longer than four years do not require a waiver];
- (b) Serve more than eight combined years within a period of 12 years on one or more committees within an agency;
- (c) Serve on more than one committee within an agency at the same time; OR
- (d) Serve on the same committee at the same time with another individual who is affiliated with the same non-Federal organization or institution in the same city.

Different committee types or appointing authorities dictate the procedures required for requesting a membership waiver. There are three separate sets of procedures for requesting a membership waiver.

Procedures are set by appointing authority and/or committee type. If you have questions, please contact your IC Committee Management Office or the Office of Federal Advisory Committee Policy for additional assistance.

1. Procedures to Request a Waiver for an Individual Nominated to Serve on a Presidential or Secretary-appointed Committee:

A request for a waiver for a nominee or combination of nominees on a nomination slate submitted to the Secretary, HHS, for approval must be submitted as a formal waiver in a memo format with the Nomination Slate Package submitted to the Office of Federal Advisory Committee Policy (OFACP). There are no streamlined waivers for Presidential or Secretary-appointed advisory committees. The membership waiver request must include:

- (a) the name of the nominee,**
- (b) the specific policy being waived (for example, excessive service), and**
- (c) the reason and a detailed explanation of why this particular individual is needed on the committee at this time, in other words, why the appointment of this individual is needed now rather than at a time a membership waiver is no longer required.**

The detailed explanation must be specific and include the nominee's expertise or experience in relation to the committee's function or upcoming committee work [why this individual is needed versus an individual that would not require a waiver].

All requests for a waiver of HHS membership policy are addressed to the Director, NIH, and must include approval/disapproval lines for the NIH Director's signature along with the date. In addition, any nominee or combination of nominees requiring a waiver will also be noted on the Advance Review Form (completed by an IC Committee Management Officer) and included with the official nomination package submitted to OFACP.

2. Procedures to Request a Waiver for an Individual Nominated to Serve as a Standing Member on an NIH Director, NIH Deputy Director, or IC Director-appointed Committee:

NIH officials have identified specific instances where a waiver request of HHS policy would be approved without the necessity of a detailed justification. The charts below (one for each of the four HHS membership restrictions) identify instances where the "streamlined" waiver process applies and where the "formal" waiver (memo format) process is required. Either process results in the same type of membership waiver under HHS policy, if approved.

**Serving as a Standing Member on More Than One NIH Committee
Streamlined versus Formal Waivers
For Advisory Committee Assignments in Different ICs***

Chart Applies to NIH Director-appointed Committees (Program Advisory Committees [PACs], Boards of Scientific Counselors [BSCs], and Initial/Integrated Review Groups [IRGs] where approval process has not been re-delegated to another Federal Official), NIH Deputy Director-appointed Committees (IRGs), and IC Director-appointed Committees (PACs, BSCs, and IRGs)

	IRG	BSC	PAC	NAC
IRG	Streamlined	Streamlined	Formal	Formal**
BSC	Streamlined	Streamlined	Formal	Formal
PAC	Formal	Formal	Streamlined	Streamlined
NAC	Formal**	Formal	Streamlined	Formal

*Different ICs – The streamlined waiver process applies to advisory committees that are in different ICs (for example, an IRG in CSR and a BSC in NCI). If the two committees are in the same IC, for example a BSC in NHLBI and an IRG in NHLBI, a formal waiver (memo format) is required.

****Formal – NIH Manual Chapter 4204-204B (Peer Review Process) [section V (Policy), C (Impartiality), 1 (Conflict of Interest), d (Undue Influence)]** states “An individual may not participate in both an application’s initial peer review and Council review, to avoid any one individual from having undue influence on the evaluation of an application. Similarly, an individual may not participate as a Mail Reviewer and fully participating SRG member evaluating the same application.” Based on this requirement, requests for membership waivers to serve on both an IRG and a Council or two Councils at the same time will generally not be considered for approval. Requests involving different ICs will be considered on a case by case basis and may include consultation with other program offices involved in peer review and council oversight. If this situation occurs, the formal waiver must include efforts that will be in place to ensure that the peer reviewer will not be involved in the review of the same applications at the Council level. Requests for service on an IRG and Council in the same IC will not be considered. If an IC IRG member is identified as a nominee for that same IC’s Council membership, it is recommended that the member complete their service on the IRG before being nominated or resign their appointment on the IRG before their service on the Council would begin rather than request a membership waiver.

Procedures to request a Streamlined Waiver – If the waiver situation falls into the streamlined category, the request for a waiver of HHS policy must be included in a statement in the Comment section of the Worksheet Report: *Waiver of Department policy is invoked for [insert full name of nominee]. Department policy being waived: A member may not serve on more than one committee at the same time [insert name of committee nominee is currently serving].*

Staff managing IC Director-appointed committees will submit a copy of the nomination package prior to the IC Director approval of the nomination slate with the request for a streamlined waiver included on

the Worksheet Report as noted above. The worksheet and other documentation will be forwarded to the NIH Director or NIH Deputy Director for approval of the waiver request.

Procedures to request a Formal Waiver [Program Advisory Committees (PACs), Boards of Scientific Counselors (BSCs), and Initial Review Groups (IRGs)] – If the waiver situation falls into the formal category, a written waiver (memo format) must be included with the nomination slate package. The waiver request must include an explanation of the nominee’s expertise or experience in relation to the committee’s function or upcoming committee work [why this individual is needed versus an individual that would not require a waiver].

Formal waiver requests for committee appointments approved by the NIH Director (PACs, BSCs, or IRGs not re-delegated), **and committee appointments approved by an IC Director (PACs and BSCs)** are addressed to the NIH Director and include approval/disapproval lines for the NIH Director’s signature and date. Staff managing IC Director-appointed committees will submit a copy of the nomination package, including the formal waiver, prior to the IC Director approval of the nomination slate. The formal waiver and other documentation will be forwarded to the NIH Director for approval of the waiver request.

Procedures to request a Formal waiver for Initial/Integrated Review Groups (IRGs) and their Subcommittees – Formal waiver requests for committee appointments approved by the NIH Deputy Director (IRGs and their subcommittees) **and appointments approved by an IC Director** (IRGs and their subcommittees) are addressed to the NIH Deputy Director and include approval/disapproval lines for the NIH Deputy Director’s signature and date. Staff managing IC Director-appointed committees will submit a copy of the nomination package, including the formal waiver, prior to the IC Director approval of the nomination slate. The formal waiver and other documentation will be forwarded to the NIH Deputy Director for approval of the waiver request.

**Serve Continuously for More Than a Full Term*
Streamlined versus Formal Waivers**

Chart Applies to NIH Director-appointed Committees (Program Advisory Committees [PACs], Boards of Scientific Counselors [BSCs], and Initial/Integrated Review Groups [IRGs] where the approval process has not been re-delegated to another Federal Official), NIH Deputy Director-appointed Committees (IRGs), and IC Director-appointed Committees (PACs, BSCs, and IRGs)

Initial Appointment	Waiver Type
Initial advisory committee appointment was for two years or less and rotation remains balanced	Streamlined
Initial advisory committee appointment was for more than two years	Formal

***Full Term** refers to the total length of time, identified in the committee’s charter, for an individual to serve as a member under a single appointment. Full terms are designated in specific years, such a four-year, five-year, or six-year term as a member of a committee/subcommittee (study section).

Procedures to request a Streamlined Waiver – If the waiver falls into the streamlined category, a statement must be included in the Comments section of the Worksheet Report: *Waiver of Department policy is invoked for [insert full name of nominee]. Department policy being waived: A member may not serve continuously for more than four years on any single advisory committee.*

Staff managing IC-Director appointed committees will submit a copy of the nomination package prior to the IC Director approval of the nomination slate with the request for a streamlined waiver included on the Worksheet Report as noted above. The worksheet and other documentation will be forwarded to the NIH Director or NIH Deputy Director for approval of the waiver request.

Procedures to request a Formal Waiver [Program Advisory Committees (PACs), Boards of Scientific Counselors (BSCs)] and Initial Review Groups (IRGs) – If the waiver situation falls into the formal category, a written waiver (memo format) must be included with the nomination slate package. The waiver request must include an explanation of the nominee’s expertise or experience in relation to the committee’s function or upcoming committee work [why this individual is needed versus an individual that would not require a waiver].

Formal waiver requests for committee appointments approved by the NIH Director (PACs, BSCs, or IRG not re-delegated), **and committee appointments approved by an IC Director (PACs and BSCs)** are addressed to the NIH Director and include approval/disapproval lines for the NIH Director’s signature and date. Staff managing IC Director-appointed committees will submit a copy of the nomination package, including the formal waiver, prior to the IC Director approval of the nomination slate. The formal waiver and other documentation will be forwarded to the NIH Director for approval of the waiver request.

Procedures to request a Formal waiver for Initial/Integrated Review Groups (IRGs) and their Subcommittees – Formal waiver requests for committee appointments approved by the NIH Deputy Director (IRGs and their subcommittees) **and appointments approved by an IC Director** (IRGs and their subcommittees) are addressed to the NIH Deputy Director and include approval/disapproval lines for the NIH Deputy Director’s signature and date. Staff managing IC Director-appointed committees will submit a copy of the nomination package, including the formal waiver, prior to the IC Director approval of the nomination slate. The formal waiver and other documentation will be forwarded to the NIH Deputy Director for approval of the waiver request.

**Excessive Service* (More than 8 years in the last 12)
Streamlined versus Formal Waivers**

Chart Applies to NIH Director-appointed Committees (Program Advisory Committees [PACs], Boards of Scientific Counselors [BSCs], and Initial/Integrated Review Groups [IRGs] where approval process has not been re-delegated to another Federal Official), NIH Deputy Director-appointed Committees (IRGs), and IC Director-appointed Committees (PACs, BSCs, and IRGs)

Length of Service	Waiver Type
More than 8 years of NIH committee service but less than 9 years in the last 12 years	Streamlined
More than 9 years of NIH committee service in the last 12 years	Formal

Excessive Service refers to the amount of service an individual has accumulated as a standing member on one or more NIH advisory committees. An accurate accounting of an individual's service history is available through the "Service History Report" located in CM IMPAC II.

Procedures to request a Streamlined Waiver – If the waiver situation falls into the streamlined category, a statement must be included in the Comments section of the Worksheet Report. *Waiver of Department policy is invoked for [insert full name of nominee]. Department policy being waived: A member may not serve more than eight combined years within a twelve year period on one or more NIH committees.*

Staff managing IC Director-appointed committees will submit a copy of the nomination package prior to the IC Director approval of the nomination slate with the request for a streamlined waiver included on the Worksheet Report as noted above. The worksheet and other documentation will be forwarded to the NIH Director or NIH Deputy Director for approval of the waiver request.

Procedures to request a Formal Waiver [Program Advisory Committees (PACs), Boards of Scientific Counselors (BSCs), or Initial Review Groups (IRGs) not re-delegated] – If the waiver situation falls into the formal category, a written waiver (memo format) must be included with the nomination slate package. The waiver request must include an explanation of the nominee's expertise or experience in relation to the committee's function or upcoming committee work [why this individual is needed versus an individual that would not require a waiver].

Formal waiver requests for committee appointments approved by the NIH Director (PACs, BSCs, or IRGs not re-delegated), **and committee appointments approved by an IC Director (PACs and BSCs)** are addressed to the NIH Director and include approval/disapproval lines for the NIH Director's signature and date. Staff managing IC Director-appointed committees will submit a copy of the nomination package, including the formal waiver, prior to the IC Director approval of the nomination slate. The formal waiver and other documentation will be forwarded to the NIH Director for approval of the waiver request.

Procedures to request a Formal waiver for Initial/Integrated Review Groups (IRGs) and their Subcommittees – Formal waiver requests for committee appointments approved by the NIH Deputy Director (IRGs and their subcommittees) **and appointments approved by an IC Director** (IRGs and their subcommittees) are addressed to the NIH Deputy Director and include approval/disapproval lines for the NIH Deputy Director's signature and date. Staff managing IC Director-appointed committees will submit a copy of the nomination package, including the formal waiver, prior to the IC Director approval of the nomination slate. The formal waiver and other documentation will be forwarded to the NIH Deputy Director for approval of the waiver request.

**Same Non-Federal Institution/Same City*
Streamlined versus Formal Waivers**

Chart Applies to NIH Director-appointed Committees (Program Advisory Committees [PACs], Boards of Scientific Counselors [BSCs], and Initial/Integrated Review Groups [IRGs] where approval process has not been re-delegated to another Federal Official), NIH Deputy Director-appointed Committees (IRGs), and IC Director-appointed Committees (PACs, BSCs, and IRGs)

Combinations	Two Nominees or one member and one Nominee*
Same Institution, Different Cities	No Waiver Required
Same Institution, Same City, Different Departments or Units	Streamlined Waiver
Same Institution, Same City, Same Department	Formal Waiver
Employee/Supervisor Relationship	Formal Waiver**
Same Institution, Same City, More than two from the same institution in the same city	Formal Waiver
Same Federal Agency	No Waiver Required

*A request for a waiver includes any combination of nominee(s) and/or current members. When analyzing institutions, all known appointments, primary/secondary [academic, clinical, and corporate] must be considered in determining if a waiver request is needed. Additional examples follow the procedures that provide additional guidance in determining if a waiver is required.

** Employee/Supervisor Relationship – It is generally not recommended that an employee and their supervisor serve on the same committee at the same time, including those from Federal agencies. There is an appearance that the employee may not provide independent advice or opinions. However, in those rare circumstances that both their expertise is required, the waiver request should contain details on the management of the situation (assignment of applications, review of laboratories, and other committee function/work).

Procedures to request a Streamlined Waiver – If the waiver falls into the streamlined category, a statement must be included in the Comments section of the Worksheet Report. *Waiver of Department policy is invoked for [insert full name of nominee]. Department policy being waived: A member may not*

serve on the same committee at the same time with another individual [insert name of other individual] from the same institution in the same city and the same department or unit, or having a supervisor/employee relationship.

Staff managing IC Director-appointed committees will submit a copy of the nomination package prior to the IC Director approval of the nomination slate with the request for a streamlined waiver included on the Worksheet Report as noted above. The worksheet and other documentation will be forwarded to the NIH Director or NIH Deputy Director for approval of the waiver request.

Procedures to request a Formal Waiver [Program Advisory Committees (PACs) Boards of Scientific Counselors (BSCs,) or Initial/Integrated Review Groups (IRGs)] – If the waiver situation falls into the formal category, a written waiver (memo format) must be included with the nomination slate package. The waiver request must include an explanation of the nominee’s expertise or experience in relation to the committee’s function or upcoming committee work [why this individual is needed versus an individual that would not require a waiver].

Formal waiver requests for committee appointments approved by the NIH Director (PACs, BSCs, and IRGs not re-delegated), **and committee appointments approved by an IC Director (PACs and BSCs)** are addressed to the NIH Director and include approval/disapproval lines for the NIH Director’s signature and date. Staff managing IC Director-appointed committees will submit a copy of the nomination package, including the formal waiver, prior to the IC Director approval of the nomination slate. The formal waiver and other documentation will be forwarded to the NIH Director for approval of the waiver request.

Procedures to request a Formal waiver for Initial/Integrated Review Groups (IRGs) and their Subcommittees – Formal waiver requests for committee appointments approved by the NIH Deputy Director (IRGs and their subcommittees) **and appointments approved by an IC Director** (IRGs and their subcommittees) are addressed to the NIH Deputy Director and include approval/disapproval lines for the NIH Deputy Director’s signature and date. Staff managing IC Director-appointed committees will submit a copy of the nomination package, including the formal waiver, prior to the IC Director approval of the nomination slate. The formal waiver and other documentation will be forwarded to the NIH Deputy Director for approval of the waiver request.

Examples

Example #1 – Member and nominee from the same institution:

Nominee	Current Member
Sandra Smith	M. Sally Jones
Associate Professor	Professor
Department of Biochemistry	Department of Pharmacology
School of Medicine	School of Medicine
Temple University	Temple University
Philadelphia, PA	Philadelphia, PA

Explanation

A waiver is required because both the current member and nominee are serving from the same institution (Temple University) in the same city (Philadelphia). The two individuals are located in different departments and would be eligible for a streamlined waiver for NIH Director and Deputy Director appointed committees.

Example #2 - Member from an institution and a nominee from an affiliated organization of the member's institution:

Nominee	Current Member
Sandra Smith	M. Sally Jones
Clinical Director	Professor
Dana Farber Cancer Institute	Department of Medicine
Boston, MA	Harvard Medical School
	Boston, MA

Explanation

A waiver is not required because the nominee is employed at an affiliated organization of the current member and does not hold a second (joint) appointment at Harvard. Note: If the nominee held a second (joint) appointment at Harvard or the member held a second (joint) appointment at Dana Farber, a waiver would be required.

Example #3 - Nominees with second (joint) appointments:

Nominee		Nominee	
Sandra Smith		M Sally Jones	
Clinical Director	Professor	Surgeon	Professor
Mass General Hospital	Dept. Of Medicine	Brigham & Women's Hospital	Dept of Biology
45 Fruit Street	Harvard University	75 Francis Street	Harvard University
Boston, MA	Boston, MA	Boston, MA	Boston, MA

Explanation

A waiver is required because both nominees are have second (joint) appointments and are employed at Harvard University. It is the responsibility of the IC Committee Management Officer to review all active employments to determine if a membership waiver is required. The two individuals are located in

different departments and would be eligible for a streamlined waiver for NIH Director and Deputy Director appointed committees

Example #4 - Nominee with a second (joint) employment at a current member’s institution:

Nominee		Current Member
Sandra Smith		M. Sally Jones
Clinical Director		Surgeon
Maine Medical Center	+	Vermont State Hospital
Department of Mental Health		Department of Infectious Diseases
Portland, ME		108 Cherry Street
		Burlington, VT
	Surgeon	
	Vermont State Hospital	
	Department of Mental Health	
	108 Cherry Street	
	Burlington, VT	

Explanation

A waiver is required because the nominee has a second (joint) employment at the same institution as the current member (Vermont State Hospital). It is the responsibility of the IC Committee Management Officer to review all active employments to determine if a membership waiver is required. The two individuals are located in different departments and would be eligible for a streamlined waiver for NIH Director and Deputy Director appointed committees.

Example #5 - Nominee and current member have second (joint) appointments at a federal organization.

Nominee		Current Member
Sandra Smith		M. Sally Jones
Professor		Professor
Department of Anatomy	+	Clinical Director
Medical College of Georgia		Dept. of Biochemistry
Augusta, GA		Morehouse School of
		Medicine
	Surgeon	Augusta, GA
	C. Norwood VA	
	Medical Center	
	Augusta, GA	
		C. Norwood VA
		Augusta, GA

Explanation

No waiver is required because both the current member and the nominee have secondary appointments at a federal institution or organization. The committee membership requirement only applies to non-federal institutions and organizations.

3. Procedures to Request a Waiver for an Individual Designated to Serve on an Individual Meeting as a Temporary or Special Emphasis Panel (SEP) Member

A request for a waiver for an individual or combination of individuals to serve as a Temporary member at an Initial/Integrated Review Committee/Subcommittee meeting or as a Special Emphasis Panel (SEP) member must be submitted as a formal waiver (memo format). There are no streamlined waiver processes for these member types. There are only two waiver situations for TEMP/SEP members:

Temporary and Special Emphasis Panel Waivers

	Temporary Member	SEP Member	Mail Reviewer
More than one Committee (same IC or Different ICs)	Formal Waiver	Formal Waiver	No Waiver
Same Institution/Same City (two or more)*	Formal Waiver	Formal Waiver	No waiver required

*Includes the addition of Temporary members in combination with standing members in attendance at the meeting.

Procedures to request a Formal waiver for Temporary or Special Emphasis Members - Formal waiver requests can be in an IC specific format or one that is generated from the QVR Waiver Request Program. **Note:** The QVR Program only looks at the roster address. SROs or other IC staff may be aware of secondary appointments that would require a membership waiver. In those cases, the information may be included in the memo or the QVR data sheet.

This policy is effective immediately. Questions on this policy should be referred to the Office of Federal Advisory Committee Policy, (301) 496-2123