

CONFLICT OF INTEREST (COI)/ETHICS PROCEDURES AND REQUIREMENTS for SPECIAL GOVERNMENT EMPLOYEES (SGEs) AND PEER REVIEWERS

COI/ETHICS PROCEDURES

SGEs

NACs/PACs/BSCs

- New SGE completes and returns OGE 450 and HHS 697
- CMO and Ex Sec review HHS 697 and advise accordingly (form is completed yearly)
- CMO reviews OGE 450 and prepares Recusal List
- CMO and Ex Sec review OGE 450 and Recusal List; CMO prepares COI Waiver/Authorization when necessary
- IC DEC reviews and signs original OGE 450 and COI Waiver
- SGE reviews most recent Recusal List and completes a COI Verification update 30 working days prior to each meeting
- CMO and Ex Sec review, update, and prepare new COI Waiver/Authorization or Addendum and/or Recusal List as necessary
- IC DEC signs Waiver/Authorization or Addendum
- CMO sends copy of signed COI Waiver/Addendum to NIH Ethics Counsel
- CMO retains original OGE 450 and COI Waiver/Addendum/Authorization/Recusal List

PEER REVIEWERS

SRGs/SEPs

All Pre-meeting and Post-meeting COI documents are generated in the Peer Review Module of the IMPAC II

- All Peer Reviewers are sent Pre-meeting COI forms to complete and sign prior to application assignment
- SRA reviews completed forms and assigns applications accordingly
- NIH Post-meeting COI forms are signed by reviewers
- Original COI documents are retained in the IC's official file

Items to be considered when determining Actual and Appearance of Conflicts of Interest for SGEs and Peer Reviewers

- Employment – Self, Spouse, Significant Other, Dependent Children, and Professional Associates
- Investments – Financial Interests of Self, Spouse, Domestic Partner, and Dependent Children
- Memberships - Professional Associations
- Adjunct Appointments
- Affiliations
- Collaborations
- Honorariums/Sponsored Travel
- Mentorships

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COI/ETHICS FORMS

<i>Forms</i>	<i>Committees</i>	NACs			PACs		BSCs	
		SGE	Fed Empl/ Ex Officio	Non- Member	SGE	Fed Empl/ Ex Officio	SGEs	Fed Empl
OGE 450		X	X		X	X	X	X
SF 278			<i>or</i> X		<i>or</i> X			<i>or</i> X
Recusal List		X	X		X	X		X
Verification of Review of Financial Interests		X	X		X	X		X
Verification Form for Federal Employees (SF278 Filers)			<i>or</i> X		<i>or</i> X			<i>or</i> X
Clearance Process to Identify and Resolve Potential Conflicts of Interest		X	X		X	X		X
COI Certification for Non-Member				X				
Post Meeting Certification		X	X					
Post Meeting Certification for Ex Officio and Alternates			X		X (when applicable)			
HHS 697 Foreign Activities Questionnaire		X	X (non-HHS)		X X (non-HHS)	X		X (non- HHS)
Conflict of Interest and Confidentiality Certification for Individuals Evaluating All NIH Intramural Programs						X		X

<i>Forms</i>	<i>Committees</i>	SRGs				SEPs		
		Non-Fed	Fed Empl	Temporary	Non- Member	Non-Fed	Fed Empl	Non- Member
Pre-Review Certification for Non-Federal Reviewers		X		X		X		
Pre-Review Certification for Federal Reviewers			X	<i>or</i> X			X	
COI Certification for Non-Member					X			X
Post Review Certification for Non- Federal and Federal Reviewers		X	X	X		X	X	

CONFLICT OF INTEREST (COI)/ETHICS PROCEDURES AND REQUIREMENTS for SPECIAL GOVERNMENT EMPLOYEES (SGEs) AND PEER REVIEWERS

EMOLUMENTS CLAUSE OF THE U.S. CONSTITUTION

SGEs

The Emoluments Clause applies at all times during an SGE's appointment.

- SGE cannot be an employee of a foreign government entity, including certain public universities or commercial enterprises owned or operated by a foreign government.
- SGE cannot receive any present, emolument, office or title from a foreign state.
 - An emolument includes salary, honoraria, transportation, per diem, household goods, shipment costs, and housing allowances.

SGE must complete Form HHS 697, Foreign Activities Questionnaire, as required by HHS Office of General Counsel, Ethics Division.

- New members receive form with appointment package.
- Current members receive form yearly. CMO sends form prior to first committee meeting of each year, with OGE 450 update/verification.

For a list of foreign entities that are and are not governed by the Emoluments Clause, please see <http://ethics.od.nih.gov/Topics/foreign.htm>. This list is noninclusive.

PEER REVIEWERS

The Emoluments Clause does not apply to Peer Reviewers.

COI TRAINING REQUIREMENTS

SGEs

- Annual ethics training is required each calendar year by the Office of Government Ethics.
- Training materials determined by Office of General Counsel, Ethics Division.
- IC CMO retains ethics training documentation.
- Annual ethics training report required by DHHS.

PEER REVIEWERS

- SRAs provide Peer Reviewers with an orientation of NIH Policy and Procedures upon initial committee appointment and prior to each IRG meeting.
- SRAs provide orientation to SEP members prior to each SEP meeting.

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COI for STATE MULTI-CAMPUS SYSTEMS and PRIVATE INSTITUTIONS and AFFILIATES

SGEs

State Multi-campus Institutions

A member employed at one campus of a State multi-university system may review applications from a separate university of the same system, provided they have no multi-campus responsibilities.

For example,

- An SGE member from California (Cal) State Fullerton may review grants from another university of the Cal State University system.
- A member of the Board of Regents of Cal State University system may not review applications from any of the campuses of Cal State unless a waiver is granted under 18 U.S.C. (b)(1) or (b)(3).

Private Institutions and Affiliates

Members may review applications submitted by an affiliate of their private institution if they:

- do not hold a joint appointment with that affiliate,
- do not have affiliate-wide responsibilities, and
- have a waiver to participate.

For example, a Professor at Harvard may review applications from Beth Israel, if above criteria is met.

For additional information see
**OFACP Policy Announcement 2001-04:
Conflict of Interest for Special Government Employees
(SGEs) from State-Multi-Campus Systems and Private
Institutions and Affiliates**

<http://www3.od.nih.gov/cmo/laws-rp-rt/index.html>

PEER REVIEWERS

Multi-Component Institutions

A non-Federal member employed by one component of a multi-component academic institution, hospital, health center, or research institute may review an application/proposal from another component of that organization if they are considered sufficiently independent.

For example,

- The separate campuses of the California State system are separate components in the same way as the separate campuses of the University of California system.
- The separate campuses of the Harvard system are considered separate components.
- The Johns Hopkins Bayview Medical Center and the School of Arts and Sciences, Homewood Campus, are separate components.
- The Johns Hopkins School of Arts and Sciences and of Engineering, Homewood Campus, are separate components.
- For purposes of this blanket waiver, the Departments of Biology and Chemistry within the School of Arts and Sciences, Johns Hopkins, are NOT separate components.

For additional information see
**OER Policy Announcement 1999-02:
Blanket Waiver of Conflict of Interest for Peer Review
Consultants - Multi-Component Institutions**

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ATTENDANCE AT CLOSED SESSIONS

	NACs	SRGs	SEPs	
SGE Committee Members	X			
Peer Review Committee Members (including Temporary Members)	X [*]	X		
Peer Reviewers Designated to Serve on SEPs			X	
Federal Officials (operational)	X	X	X	
Federal Officials (need to know)	X	X	X	
Non-Member Attendees (ad hoc consultants), with approved COI Certification	**			
Other:	X			
Newly appointed Council members, with approved OGE 450 form	*** X	*** X	*** X	
Council nominees, with approved OGE 450 form	*** X	*** X	*** X	
Individuals assisting members with disabilities	X	X	X	

* May attend only for the discussion of general peer review issues or SRG operations.

** May attend as a reviewer, presenter, or discussant.

*** May attend for training/orientation.