

NIH CONFLICT OF INTEREST RULES: INFORMATION FOR REVIEWERS OF NIH APPLICATIONS AND R&D CONTRACT PROPOSALS

The NIH peer review system relies on the professionalism of each reviewer to identify any conflict of interest (COI) or apparent COI that may affect or appear to affect the integrity of the NIH peer review process. The NIH COI rules for initial peer review are derived from federal regulations governing the Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects (42 CFR Part 52h at http://grants.nih.gov/grants/policy/fed_reg_peer_rev_20040115.pdf), and NIH policy Guide Notice (NOT-OD-11-120 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-120.html>). Federal employees participating in peer review are subject to a comprehensive set of statutes and regulations governing their conduct in addition to NIH policy regarding their selection and use in the peer review process.

Non-federal reviewers - You are personally responsible for:

- identifying and certifying on the pre-meeting and post-meeting Conflict of Interest Certification Forms that you:
 - have identified any application or proposal with which you have a COI or appearance of COI (see "Managing COI or Appearance of COI", below).
 - recused yourself from the review of any application or proposal pending review in the Scientific Review Group where your participation constitutes a real or apparent COI. In addition, the NIH may determine that a particular situation involves a COI and require that the potential reviewer not be involved in the review of the application(s) or proposal(s) in question.
- certifying that you have read the Confidentiality and Non-Disclosure Rules and will maintain the confidentiality of the peer review process (see the Confidentiality Agreement).

Federal reviewers - You must:

- certify on the pre-meeting and post-meeting Conflict of Interest Certification Forms that you have received information regarding the COI rules applicable to Federal employees and will/did recuse yourself from any evaluation in relation to which you have/had an actual or apparent conflict of interest, or as otherwise required by NIH policy regarding the selection and use of federal employee reviewers.
- certify that you have read the Confidentiality and Non-Disclosure Rules and will maintain the confidentiality of the peer review process (see the Confidentiality Agreement).

Managing COI or Appearance of COI

1. Individuals Participating with Major Professional Roles

An individual considered to be participating in a project with a major professional role contributes to the scientific development or execution of the project in a substantive, measurable way, whether or not compensation is requested. Even where a Federal employee's participation in the review would not violate government ethics rules, if s/he is identified as someone who will participate in a project with a major professional role, s/he may not serve as a fully participating member of the SRG where the application in question is reviewed (i.e., "out of the SRG" or "may not serve"). In addition, an individual with a primary appointment in the same component of a multi-component organization as an individual listed on the application with a major professional role may not participate in the review of that application ("out of the room" or "may not review").

Individuals participating with major professional roles include:

- the Program Director/Principal Investigator (PD/PI) or one of multiple PDs/Pis;
- individuals listed on a single-project application as Senior/Key Personnel, Other Significant Contributors, collaborators{1}, and consultants{1};
- individuals with leadership roles in multi-site or multi-component applications or projects, such as Project/Site/Core Directors, Senior/Key Personnel, Other Significant Contributors, collaborators{1}, and consultants{1} at the level of the overall application. Senior/Key Personnel, Other Significant Contributors, collaborators and consultants listed under individual

{1} A consultant or collaborator who has received or could receive a direct financial benefit of any amount deriving from an application under review, or has received or could receive a financial benefit from the applicant institution or PD/PI that in the aggregate exceeds \$10,000/year, is considered to be participating with a major professional role.

- a sponsor or mentor for an applicant or candidate whose application for a fellowship or career development award is undergoing review;
- the originators and planning group members for a conference/meeting grant application; and
- members of an Advisory Board (AB) for a single project or single institution program, for a multi-component consortium or network, or for individual(s) with a leadership role in a multi-site or multi-component project. The SRO will determine whether the level of participation by the AB member is sufficient to eliminate his/her participation on the SRG.

2. Professional Relationships

An SRG member, including a Federal employee (where participation in the review would not violate government ethics rules), may serve on the SRG but may not participate in the review of an application ("out of the room"), in the absence of a waiver granted by the DDER if the reviewer:

- within the preceding three years, has collaborated with, co-authored a publication(s)^{2} with, and/or mentored or trained the PD/PI, one of multiple PDs/Pis, or an individual named on the application as participating with a major professional role;
- is in collaboration, is negotiating collaboration, or is preparing an application(s) or publication(s) with the PD/PI, with one of multiple PDs/Pis, or with an individual named in the application as participating with a major professional role;
- writes a reference letter for an applicant or candidate to accompany a fellowship or career award application and that application is the one in question (however, other SRG members who are from the SRG member's institution, NIH IC, or agency may review the application);
- writes a letter of general support or enthusiasm for the application in question but plays no substantive role in the proposed work;
- is named as a speaker in a conference/meeting grant application;
- participates with a leadership role in another multi-site or multi-component application or project (Application "X") and the PD/PI or one of multiple PDs/Pis on the application or project in the SRG (Application "Y") also participates with a leadership role in the same multi-site or multi-component application or project (Application "X");
- serves as a member of an AB for a component within a multi-component consortium or network, or another project by the same applicant(s), unless the SRO determines that the level of participation by the AB member is sufficiently minor as to allow his/her participation in the review of the application;
- serves as a member of a DSMB for the project or investigator(s), unless the SRO determines that the level of participation by the DSMB member is sufficiently minor as to allow his/her participation in the review of the application; or
- has a primary professional appointment in the same organizational component/school of a multi-component academic institution, hospital, health center, or research institute as that of a named individual listed on the application or project as participating with a major professional role. Situations involving a secondary appointment of a named individual and an SRG member at the same component of a multi-component academic institution, hospital, health center or research institute will be assessed by the SRO on a case-by-case basis for COI.

3. Applicants to an RFA

Unless a deviation from a limitation set forth in this Section B is granted by the DDER, an investigator who participates with a major professional role on an application submitted in response to an RFA, or a Federal employee subject to one of the above-stated limitations in relation to an application submitted in response to an RFA, may not serve as a reviewer of that application or other applications submitted in response to the same RFA.

4. SRG Membership

An SRG that meets regularly may not be objective as a group about evaluating the work of one of its members. In such a case, a member's application or an application that lists the member as participating with a major professional role will be reviewed by another qualified SRG to ensure a competent and objective review. In addition, an application that is from an individual who serves regularly on a recurring SEP, or lists such an individual as participating with a major professional role, may create an appearance of COI for review by that SEP. The SRO will monitor such situations for potential COI.

5. Exceptions

Multi-component Institutions. For non-Federal reviewers, the DDER has determined that separate organizational components/schools of multi-component academic institutions, hospitals, health centers, and research institutions, as well as

^{2} See Discussion 5., "Individuals Participating with Minor Professional Roles", concerning co-authorship of a review article, position paper, or professional group or conference report.

NIH/OER/OEP (Approved 9/20/2011 for implementation by January 25, 2012)

different NIH ICs{3} and Federal agencies, are sufficiently independent that an employee of one component serving on an SRG can review an application from another component, if the reviewer has no responsibilities at the institution that would significantly affect the other component and any other real or apparent COI is resolved. For example:

- the separate campuses of the California State system are considered separate components in the same way that the separate campuses of the University of California system are so noted in 42 CFR Part 52h (http://grants.nih.gov/grants/policy/fed_reg_peer_rev_20040115.pdf);
- the separate affiliates of the Harvard system are considered separate components;
- the Johns Hopkins Bayview Medical Center and the School of Arts and Sciences, Homewood Campus, are considered separate components;
- the Johns Hopkins Schools of Arts and Sciences and of Engineering, Homewood Campus, are considered separate components; but
- the Departments of Biology and Chemistry within the School of Arts and Sciences of the same academic institution are not considered separate components

A Federal employee who has, under government ethics rules, a covered relationship with or financial interest in an applicant institution may not participate in the review of an application even if the institution is a multi-component institution.

Applicant Institution. The DDER has determined that an SRG member who is named in an application but has no other affiliation with the applicant institution may participate in the review of other applications from that applicant institution, provided that any other real or apparent COI described in Part B of this announcement is resolved. Federal reviewers must also ensure any real or apparent COI under government ethics rules is resolved by appropriate officials consistent with agency delegations of authority.

Individuals Participating with Minor Professional Roles. An individual listed in an application as participating with a minor professional role does not contribute to the scientific development or execution of the project in a substantive, measurable way and may review the application provided that any other real or apparent COI described in Part B of this announcement is resolved. Federal reviewers also must ensure that any real or apparent COI under government ethics rules is resolved by appropriate officials consistent with agency delegations of authority. Further, an SRG member from the same institution as that of an individual listed with a minor professional role may review the application, provided that any other real or apparent COI is resolved. Similarly, unless there is another unresolved real or apparent COI, an SRG member may review an application if s/he:

- supplies a resource or service to the applicant, and that resource or service is freely available to anyone in the scientific community;
- donates data, specimens or other resources to a central repository or consortium effort to which an individual(s) named on the application also donates data, specimens or other resources;
- is from the institution of the applicant, originators, planning group members, or proposed speakers for/on a conference/meeting grant application;
- co-authored a review article, position paper, professional group or conference report with the PD/PI, one of multiple PDs/Pis, or an individual listed on the application as participating with either a major or minor role;
- is from an institution that is part of a multicenter network (e.g., accrual sites for a multi-center clinical trial) or consortium (e.g., Genome Wide Association Study) that includes the applicant institution, where the SRG member is not involved in the work of the network or consortium;
- is in collaboration with an individual named in the application as a collaborator of or consultant for a PD/PI, as a collaborator of or consultant for one of multiple PDs/Pis, or as a collaborator or consultant of other individuals named in the application as participating with a major professional role{1};
- participates with a minor professional role in a multi-site or multi-component application or project (Application "X") and the PD/PI or one of multiple PDs/Pis on an application or project in the SRG (Application "Y") also participates with a minor role in the other multi-site or multi-component application or project (Application "X"). Key Personnel listed on individual components of multi-site or multi-component applications are considered to participate with a minor role in that application; or
- has a primary appointment in the same organizational component/school of a multi-component academic institution, hospital, health center, or research institute as an individual listed in an application as participating with a minor professional role.

Mail Reviewers. COI or the appearance of COI for Mail Reviewers is managed only for those applications that they have been asked to evaluate, not for all applications pending review in the SRG.

Howard Hughes Medical Institute (HHMI). HHMI peer reviewers serving on SRGs may review applications from other HHMI investigators provided they do not work at the same component/school of a multi-component academic institution and no other COI or appearance of COI exists.

{3} Members of the NIH Intramural Research Program (IRP) may not participate in the review of an application involving another member of the NIH IRP participating with a major professional role in an application for an allocation from the NIH Common Fund, regardless of IC affiliation, unless a deviation is granted by the DDER.