

Maintaining Integrity in NIH Peer Review: Responsibilities and Consequences

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Key Dates

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Related Announcements

[NOT-OD-14-073](#)

[NOT-OD-15-106](#)

Issued by

National Institutes of Health ([NIH](#))

Purpose

Maintaining integrity- including confidentiality and security - in the peer review process is essential for exchanging scientific opinions and evaluations without fear of reprisal; protecting trade secrets or other proprietary, sensitive and/or confidential information; and providing reliable input to the agency about research projects to support. In addition, maintaining integrity in the peer review process is important for maintaining public trust in science.

This Notice reminds all participants in the NIH peer review process of possible consequences that may ensue and actions that the NIH (in coordination with other offices) may take in response to a breach of integrity in peer review.

Program Directors/Principal Investigators, Officials of Applicant Institutions/Offerors, and Other Individuals Named in Applications or Proposals

Officials of applicant institutions or offerors, Program Directors/Principal Investigators, and other individuals named in applications or proposals:

- Should not contact reviewers on the study section evaluating their application or proposal to request or provide information or materials related to the review, or to otherwise attempt to influence the outcome of the review or the reviewer(s), or to access information or materials related to the review by any other means until/unless provided directly to them through NIH-approved communication channels. The only acceptable process for communication about an application is through the NIH Scientific Review Officer (SRO) who is managing the study section; the only acceptable process for communication about an R&D contract proposal is through the NIH Contracting Officer (CO) in charge of the solicitation.
- Should not send information or data directly to a reviewer on the study section evaluating his/her application or proposal. The only acceptable processes for submitting post-submission materials for applications are outlined in [NOT-OD-17-066](#).

- Should immediately contact the SRO who is managing the review of his/her application or proposal if contacted by a reviewer or by an individual named in another application or proposal for purposes of obtaining or exchanging information outside of the channels described above.

Peer Reviewers and Advisory Council Members

Each NIH peer reviewer must read the [NIH Confidentiality and Non-disclosure Rules: Information for Reviewers](#), and before gaining access to information about the applications, proposals, or meetings must certify a Confidentiality Agreement that he or she fully understands and will comply with the confidential nature of the review process (See Appendix below). Members of NIH Advisory Councils must submit Confidential Financial Disclosure statements and certify a similar Confidentiality Agreement. Additional certifications before and after the meetings for conflicts of interest also include confidentiality (see Appendix).

When certifying the Confidentiality Agreements, each peer reviewer agrees, under penalty of perjury, 18 U.S.C. §1001, to maintain confidentiality in peer review. [18 USC § 1001](#) states:

"Except as otherwise provided in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully—

- (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact;
- (2) makes any materially false, fictitious, or fraudulent statement or representation; or
- (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry;

shall be fined under this title, imprisoned not more than 5 years or, if the offense involves international or domestic terrorism (as defined in section 2331), imprisoned not more than 8 years, or both."

In addition, reviewers are expected to immediately notify the SRO who is managing the review of the relevant application or proposal if they are contacted for purposes of obtaining or exchanging information outside of the channels described above.

Possible Consequences

If the NIH determines that a situation involves a breach of integrity (including confidentiality and/or security) in the peer review process, the NIH in coordination with other offices may take action(s) including, but not limited to:

- notifying the individuals and institutions involved.
- terminating the reviewer's or Council member's service in peer review.
- pursuing a referral for government-wide suspension or debarment.

- referring the matter to the NIH Office of Management Assessment and possibly to the Office of Inspector General, U.S. Department of Health and Human Services, which could result in criminal penalties, fines, imprisonment, and/or other action(s).

Additional Information

For information on additional, applicable laws, regulations, and policies, as well as possible consequences for violations, see Integrity and [Confidentiality in NIH Peer Review](#).

Inquiries

Please direct all inquiries to:

Sally A. Amero, Ph.D.
NIH Review Policy Officer
ReviewPolicyOfficer@mail.nih.gov

Appendix

Below are the NIH Confidentiality and Nondisclosure Rules for Reviewers of NIH Grant Applications and R&D Contract Proposals, as well as the pre- and post-meeting certifications. These documents are available on the NIH [Consolidated List of Reviewer Documents](#) website.

Before Gaining Access to Applications, Proposals, or Meeting Information

NIH Confidentiality and Nondisclosure Rules: Information for Reviewers of NIH Grant Applications and R&D Contract Proposals

Rules related to the confidentiality of information disclosed to advisory committee members in the course of NIH peer review prohibit a peer reviewer serving on an NIH peer review committee from, among other actions:

- Sharing applications, proposals, or meeting materials with anyone who has not been officially designated to participate in the peer review meeting, including but not limited to colleagues, lab members, fellows, students, applicants, offerors or employees of an offeror.
- Granting anyone who has not been officially designated to participate in the peer review process access to any NIH secure computer system or advisory committee meeting using his or her password or credentials, or through shared communication.
- Disclosing, in any manner, information about the deliberations, discussions, evaluations, or documents to anyone who has not been officially designated to participate in the peer review meeting, including but not limited to a colleague, lab member, fellow, student, applicant, offeror or employee of an offeror.

- Disclosing, in any manner, information about the deliberations, discussions, or evaluations related to an application or proposal to another member who has declared a real or apparent conflict of interest (consistent with the NIH peer review regulations at 42 CFR 52h) with that application or proposal.
- Using information contained in an application or proposal for his/her personal benefit or making such information available for the personal benefit of any other individual or organization.
- Disclosing procurement information prior to the award of a contract.
- Participating in NIH peer review without signing a confidentiality certification, below.

The NIH may take steps in response to a violation of the above rules, in order to preserve the integrity of the NIH review process. Depending on the specific circumstances, such steps may include but not be limited to:

- Notifying or requesting information from a reviewer's institution.
- Terminating a reviewer's service.
- Notifying the NIH Office of Management Assessment (OMA) with possible referral to the U.S. Department of Health and Human Services Office of Inspector General (OIG).
- Pursuing a referral for government-wide suspension or debarment.

Certification

I certify that I have read, and understand, the "NIH Confidentiality and Non-Disclosure Rules: Information for Reviewers" above. With the understanding that any materially false, fictitious, or fraudulent statement or representation may subject me to criminal, civil, or administrative penalties (18 USC 1001), I certify that I fully understand the confidential nature of the NIH peer review process, including reviewer recruitment, and agree:

(1) to destroy, delete, and/or return all materials related to applications or proposals, associated materials made available to reviewers, information and materials related to the recruitment process and reviews, reviewers' evaluations, and discussions during review meetings;

(2) not to grant anyone who has not been officially designated to participate in the peer review meeting access to any NIH secure computer system or peer review meeting;

(3) not to disclose or discuss the applications or proposals, associated materials made available to reviewers, information and materials related to the recruitment process and reviews, reviewers' evaluations, and discussions during review meetings with any other individual except as authorized by the Scientific Review Officer (SRO) or other designated NIH official;

(4) not to disclose information about the committee deliberations, discussions, or evaluations related to an application or proposal to another member who has declared a real or apparent conflict of

interest (consistent with the NIH peer review regulations at 42 CFR 52h) with that application or proposal;

(5) not to use information contained in an application or proposal for my personal benefit or make such information available for the personal benefit of any other individual or organization;

(6) not to disclose procurement information prior to the award of a contract; and

(7) to refer all inquiries concerning the recruitment or review, including inquiries related to these Confidentiality and Nondisclosure Rules and/or Certification, to the SRO or other designated NIH official.

I Agree/Cancel

Pre-Meeting Certification

Pre-Meeting Conflict of Interest Certification

I certify that I have read and that I understand the attached "NIH Conflict of Interest Rules: Information for Reviewers of NIH Applications and R&D Contract Proposals". Under penalty of perjury (US Code Title 18 chapter 47 section 1001), I certify that to the best of my knowledge I have disclosed all conflicts of interest that I may have with the applications or R&D contract proposals and I fully understand the confidential nature of the review process and agree: (1) to destroy or return all materials related to it; (2) not to disclose or discuss the materials associated with the review, my evaluation, or the review meeting with any other individual except as authorized by the Scientific Review Officer (SRO) or other designated NIH official; (3) not to disclose procurement information prior to the award of a contract; and (4) to refer all inquiries concerning the review to the SRO or other designated NIH official.

Post-Meeting Conflict of Interest Certification

Under penalty of perjury (US Code Title 18 Chapter 47 section 1001), I fully understand the confidential nature of the review process and certify that in the review above I did not participate in an evaluation of any application or proposal with which I knowingly had a conflict of interest.