

NIH CONFLICT OF INTEREST, CONFIDENTIALITY AND NON DISCLOSURE RULES: INFORMATION FOR REVIEWERS OF GRANT APPLICATIONS AND R&D CONTRACT PROPOSALS

As reviewers themselves are most familiar with their own situations, it is their personal responsibility: (1) to alert the Scientific Review Administrator (SRA) to any possible conflict of interest situation, whether real or apparent, that may impact on the review, and (2) to identify and certify on the pre-meeting and post-meeting Conflict of Interest Certification Forms associated with this information sheet, (a) any application where they have a conflict of interest, and (b) that they will not be, and have not been, involved in the review of any application where their participation constitutes a conflict of interest. Reviewers must also certify that they will maintain the confidentiality of the proceedings and associated materials and that they will not disclose to another individual any matter or information related to the review proceedings. In addition, the NIH may determine that a particular situation involves a conflict of interest and require that the potential reviewer not be involved in the review of the application(s) or proposal(s) in question.

Where permissible by regulation, the agency head (Director, NIH), or his/her designee may grant a waiver relating to the real conflict of interest requirements. Before a waiver can be granted, it must be determined that there are no other practical means for securing appropriate expert advice to provide a competent review of an application or proposal, and that the real conflict of interest is not so substantial as to be likely to affect the integrity of the advice to be provided by the reviewer.

All reviewers are covered by this information sheet and associated Certification Forms. Membership on a scientific review group does not make an individual an employee or officer of the Federal Government. This information sheet and associated Certification Form do not apply to individuals serving on National Advisory Councils or Boards, Boards of Scientific Counselors, or Program Advisory Committees. When Federal Employees serve as reviewers, they are, in addition, covered by 18 USC 201-216, 5 CFR Part 2635, 5CFR Part 5501, and Executive Order 12674 as amended. The Public Health Service Act allows up to 25% of a scientific review group to be Federal employees.

There are several bases for a conflict of interest: employment, financial benefit, personal relationships, professional relationships or other interests. If applicable, any one condition may serve to disqualify a reviewer from participating in the review of an application or proposal. **A conflict of interest may be real or apparent.**

The following guidance and definitions, derived from federal regulations governing the Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects (42 CFR Part 52h), will assist you in determining whether you are faced with a real or apparent conflict of interest. The guidance is not all-inclusive, due to the variety of possible conflicts of interest. Therefore, it is important that you should consult the SRA in charge of the meeting when there is any question about your participation in a review.

GUIDANCE AND DEFINITIONS

A Conflict Of Interest in scientific peer review exists when a reviewer has an interest in a grant or cooperative agreement application or an R&D contract proposal that is likely to bias his or her evaluation of it. A reviewer who has a real conflict of interest with an application or proposal may not participate in its review.

Real Conflict Of Interest means a reviewer or a close relative or professional associate of the reviewer has a financial or other interest in an application or proposal that is known to the reviewer and is likely to bias the reviewer's evaluation of that application or proposal as determined by the SRA managing the review, as acknowledged by the reviewer, or as prescribed by 42 CFR 52h as follows:

A reviewer shall have a real conflict of interest if he/she or a close relative or professional associate of the reviewer: (1) has received or could receive a direct financial benefit of any amount deriving from an application or proposal under review; (2) has received or could receive a financial benefit from the applicant institution, offeror or principal investigator that in the aggregate exceeds \$10,000 per year (for reviewers who are federal employees the amount is \$15,000 per year); this amount includes honoraria, fees, stock or other financial benefit, and additionally includes the current value of the reviewer's already existing stock holdings, apart from any direct financial benefit deriving from an application or proposal under review; or (3) has any other interest in the application or proposal that is likely to bias the reviewer's evaluation of that application or proposal.

Regardless of the level of financial involvement or other interest, if the reviewer feels unable to provide objective advice, he/she must recuse him/herself from the review of the application or proposal at issue. The peer review system relies on the professionalism of each reviewer to identify to the SRA any real or apparent conflicts of interest that are likely to bias the reviewer's evaluation of an application or proposal.

Employment: A reviewer who is a salaried employee, whether full-time or part-time, of the applicant institution, offeror, or principal investigator, or is negotiating for employment, shall be considered to have a real conflict of interest with regard to an application/proposal from that organization or principal investigator. The Director of NIH or designee may determine there is no real conflict of interest or an appearance of a conflict of interest where the components of a large or multi-component organization are sufficiently independent to constitute, in effect, separate organizations, provided that the reviewer has no responsibilities at the institution that would significantly affect the other component. Membership on a scientific review group does not make an individual an employee or officer of the Federal Government.

Financial Benefit: See definition of Real Conflict of Interest above.

Personal Relationships (Relatives): A close relative means a parent, spouse, sibling, son or daughter or domestic partner. A conflict of interest exists if a close relative of a reviewer submits an application or proposal, or receives or could receive financial benefits from or provides financial benefits to an applicant or offeror. In such case, it will be treated as the reviewer's financial benefit.

Professional Associates: Professional associate means any colleague, scientific mentor, or student with whom the peer reviewer is currently conducting research or other significant professional activities or with whom the member has conducted such activities within three years of the date of the review.

Standing Review Group Membership: When a scientific review group meets regularly, a relationship among the individual members exists; therefore, the group as a whole may not be objective about evaluating the work of one of its members. In such a case, a member's application or proposal will be reviewed by another qualified review group to insure that a competent and objective review is obtained.

Longstanding Disagreements: A conflict of interest may exist where a potential reviewer has had longstanding scientific or personal differences with an applicant.

Multi-Site Or Multi-Component Project: An individual serving as either the principal investigator or key personnel on one component of a multi-site or multi-component project has a conflict of interest with all of the applications or proposals from all investigators or key personnel associated with the project. The individual should be considered a professional associate when evaluating applications or proposals submitted by the other participants in the project.

Request For Applications (RFA) Or Request For Proposals (RFP): Persons serving as the principal investigator or key personnel on an application submitted in response to an RFA or on a proposal in response to an RFP are generally considered to have a conflict of interest with all of the applications or proposals submitted in response to the RFA or RFP. However, if no other reviewer is available with the expertise necessary to ensure a competent and fair review, a waiver may be granted by the Director of NIH or his/her designee that will permit an individual to review only those applications or proposals with which he/she has no conflict of interest that is likely to affect the integrity of the advice to be provided by the reviewer.

Appearance Of A Conflict Of Interest means that a reviewer or close relative or professional associate of the reviewer has a financial or other interest in an application or proposal that is known to the reviewer or the SRA managing the review and would cause a reasonable person to question the reviewer's impartiality if he or she were to participate in the review. The SRA will evaluate the appearance of a conflict of interest and determine whether or not the interest would likely bias the reviewer's evaluation of the application or proposal. Where there is an appearance of conflict of interest, but not sufficient grounds for disqualifying the reviewer, the SRA in charge of the review will document: (1) that there is no real conflict of interest; and (2) that, at the time of the review, no practical alternative exists for obtaining the necessary scientific advice from the reviewer with the apparent conflict.

Waivers If no other reviewer is available with the expertise necessary to ensure a competent review, a waiver may be granted by the Director of NIH or his/her designee to allow participation in the review.

CONFIDENTIALITY AND NON-DISCLOSURE OF MATERIALS AND PROCEEDINGS

The applications and proposals and associated materials made available to reviewers, as well as the discussions that take place during review meetings are strictly confidential and must not be disclosed to or discussed with any one who has not been officially designated to participate in the review process. In addition, disclosure of procurement information prior to the award of a contract is prohibited by the Procurement Integrity Act.

CERTIFICATION

All reviewers must certify that they have read these instructions on "NIH Conflict of Interest, Confidentiality, and Non-Disclosure Rules and Information for Reviewers." Under penalty of perjury (US Code Title 18 chapter 47 section 1001), the reviewer must certify that, to the best of his/her knowledge, he/she has disclosed all conflicts of interest that he/she may have with the applications or R&D contract proposals and he/she fully understands the confidential nature of the review process and agrees: (1) to destroy or return all materials related to it; (2) not to disclose or discuss the materials associated with the review, their evaluation, or the review meeting with any other individual except as authorized by the SRA 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 SRA or other designated NIH official.