

§ 52h.3

42 CFR Ch. I (10–1–25 Edition)

(o) *Project concept* means the basic purpose, scope, and objectives of the project.

(p) *Project period* has the same meaning as in 42 CFR part 52.

(q) *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 government official managing the review (the Scientific Review Administrator, or equivalent), as acknowledged by the reviewer, or as prescribed by this part. 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) Apart from any direct financial benefit deriving from an application or proposal under review, 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; this amount includes honoraria, fees, stock or other financial benefit, and additionally includes the current value of the reviewer's already existing stock holdings. The Director, NIH, may amend the dollar threshold periodically, as appropriate, after public notice and comment; 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 designated government official any real or apparent conflicts of interest that are likely to bias the reviewer's evaluation of an application or proposal.

(r) *Request for proposals* means a Government solicitation to prospective offerors, under procedures for negotiated contracts, to submit a proposal

to fulfill specific agency requirements based on terms and conditions defined in the request for proposals. The request for proposals contains information sufficient to enable all offerors to prepare proposals, and is as complete as possible with respect to: nature of work to be performed; descriptions and specifications of items to be delivered; performance schedule; special requirements clauses, or other circumstances affecting the contract; format for cost proposals; and evaluation criteria by which the proposals will be evaluated.

(s) *Research* has the same meaning as in 42 CFR part 52.

(t) *Research and development contract project* means an identified, circumscribed activity, involving a single contract or two or more similar, related, or interdependent contracts, intended and designed to acquire new or fuller knowledge and understanding in the areas of biomedical or behavioral research and/or to use such knowledge and understanding to develop useful materials, devices, systems, or methods.

(u) *Scientific review group* has the same meaning as peer review group, which is defined in paragraph (k) of this section.

(v) *Solicited contract proposal* has the same meaning as the definition of offer in 48 CFR 2.101.

(w) *Unsolicited contract proposal* has the same meaning as unsolicited proposal in 48 CFR 15.601.

§ 52h.3 Establishment and operation of peer review groups.

(a) To the extent applicable, the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2) and chapter 9 of the DHHS General Administration Manual¹ shall govern the establishment and operation of peer review groups.

(b) Subject to § 52h.5 and paragraph (a) of this section, the Director will

¹The DHHS General Administration Manual is available for public inspection and copying at the Department's information centers listed in 45 CFR 5.31 and may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

adopt procedures for the conduct of reviews and the formulation of recommendations under §§ 52h.7, 52h.9, and 52h.10.

§ 52h.4 Composition of peer review groups.

(a) To the extent applicable, the selection and appointment of members of peer review groups and their terms of service shall be governed by chapter 9 of the DHHS General Administration Manual.

(b) Subject to paragraph (a) of this section, members will be selected based upon their training and experience in relevant scientific or technical fields, or upon their qualifications as authorities knowledgeable in the various disciplines and fields related to the scientific areas under review, taking into account, among other factors:

(1) The level of formal scientific or technical education completed or experience acquired by the individual;

(2) The extent to which the individual has engaged in relevant research, the capacities (e.g., principal investigator, assistant) in which the individual has done so, and the quality of the research;

(3) Recognition as reflected by awards and other honors received from scientific and professional organizations; and

(4) The need for the group to have included within its membership experts from various areas of specialization within relevant scientific or technical fields, or authorities knowledgeable in the various disciplines and fields related to the scientific areas under review.

(c) Except as otherwise provided by law, not more than one-fourth of the members of any peer review group to which this part applies may be officers or employees of the United States. Being a member of a scientific peer review group does not make an individual an officer or employee of the United States.

§ 52h.5 Conflict of interest.

(a) This section applies only to conflicts of interest involving members of peer review groups. This section does not cover individuals serving on National Advisory Councils or Boards,

Boards of Scientific Counselors, or Program Advisory Committees who, if not already officers or employees of the United States, are special Government employees and covered by title 18 of the United States Code, the Office of Government Ethics Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635), and Executive Order 11222, as amended. For those federal employees serving on peer review groups, in accordance with § 52h.4, the requirements of title 18 of the United States Code, 5 CFR part 2635 and Executive Order 12674, as modified by Executive Order 12731, apply.

(b) A reviewer with a real conflict of interest must recuse him/herself from the review of the application or proposal, except as otherwise provided in this section.

(1) 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, except that the Director may determine there is no real conflict of interest or an appearance of a conflict of interest where the components of a large or multicomponent 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.

(2) Where a reviewer's real conflict of interest is based upon the financial or other interest of a close relative or professional associate of the reviewer, that reviewer must recuse him/herself, unless the Director provides a waiver in accordance with paragraph (b)(4) of this section.

(3) For contract proposal reviews, an individual with a real conflict of interest in a particular proposal(s) is generally not permitted to participate in the review of any proposals responding to the same request for proposals. However, if there is no other qualified reviewer available having that individual's expertise and that expertise is essential to ensure a competent and fair review, a waiver may be granted by the