

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 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

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.

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 Director to permit that individual to serve as a reviewer of those proposals with which the reviewer has no conflict, while recusing him/herself from the review of any particular proposal(s) in which there is a conflict of interest.

(4) The Director may waive any of the requirements in paragraph (b) of this section relating to a real conflict of interest if the Director determines that there are no other practical means

for securing appropriate expert advice on a particular grant or cooperative agreement application, contract project, or contract 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.

(c) Any appearance of a conflict of interest will result in recusal of the reviewer, unless the Director provides a waiver, determining that it would be difficult or impractical to carry out the review otherwise, and the integrity of the review process would not be impaired by the reviewer's participation.

(d) When a peer review group meets regularly it is assumed that a relationship among individual reviewers in the group exists and that 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 shall be reviewed by another qualified review group to ensure that a competent and objective review is obtained.

(e) When a member of a peer review group participates in or is present during the concept review of a contract proposal that occurs after release of the solicitation, as described under § 52h.10(b), but before receipt of proposals, the member is not considered to have a real conflict of interest as described in paragraph (b) of this section, but is subject to paragraph (c) of this section concerning appearance of conflict of interest if the member is planning to respond to the solicitation. When the concept review occurs after receipt of proposals, paragraph (b) applies.

(f) No member of a peer review group may participate in any review of a specific grant application or contract project for which the member has had or is expected to have any other responsibility or involvement (whether pre-award or post-award) as an officer or employee of the United States.

(g) The Director may periodically issue guidance to the government officials responsible for managing reviews and reviewers on what interests would constitute a real conflict of interest or an appearance of a conflict of interest.