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.

§ 52h.6 Availability of information.

(a) Transcripts, minutes, and other documents made available to or prepared for or by a peer review group will be available for public inspection and copying to the extent provided by the Freedom of Information Act, as amended (5 U.S.C. 552), the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), the Privacy Act of 1974, as amended (5 U.S.C. 552a), and implementing DHHS regulations (45 CFR parts 5, 5b).

(b) Meetings of peer review groups reviewing grant applications or contract proposals are closed to the public in accordance with sections 552b(c)(4) and 552b(c)(6) of the Government in the Sunshine Act, as amended (5 U.S.C. 552b(c)(4) and 552b(c)(6)) and section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2). Documents made available to, or prepared for or by peer review groups that contain trade secrets or commercial or financial information obtained from a person that is privileged or confidential, and personal information concerning individuals associated with applications or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, are exempt from disclosure in accordance with the Freedom of Information Act, as amended (5 U.S.C. 552(b)(4) and 552(b)(6)).

(c) Meetings of peer review groups reviewing contract project concepts are open to the public in accordance with the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2) and the Government in the Sunshine Act, as amended (5 U.S.C. 552b).

§ 52h.7 What matters must be reviewed for grants?

(a) Except as otherwise provided by law, no awarding official shall award a grant based upon an application covered by this part unless the application has been reviewed by a peer review group in accordance with the provisions of this part and the group has made recommendations concerning the scientific merit of that application. In addition, where under applicable law an awarding official is required to secure the approval or advice of a national council or board concerning an application, the application may not be considered by the council or board unless it has been reviewed by the appropriate peer review group, in accordance with the provisions of this part, and the group has made recommendations concerning the scientific merit of the application, except where the council or board is the peer review group.

(b) Except to the extent otherwise provided by law, recommendations by peer review groups are advisory only and not binding on the awarding official or the national advisory council or board.

§ 52h.8 What are the review criteria for grants?

In carrying out its review under § 52h.7, the scientific peer review group shall assess the overall impact that the project could have on the research field involved, taking into account, among other pertinent factors:

(a) The significance of the goals of the proposed research, from a scientific or technical standpoint;

(b) The adequacy of the approach and methodology proposed to carry out the research;

(c) The innovativeness and originality of the proposed research;