

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 Free-

dom 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;

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(d) The qualifications and experience of the principal investigator and proposed staff;

(e) The scientific environment and reasonable availability of resources necessary to the research;

(f) The adequacy of plans to include both genders, minorities, children and special populations as appropriate for the scientific goals of the research;

(g) The reasonableness of the proposed budget and duration in relation to the proposed research; and

(h) The adequacy of the proposed protection for humans, animals, and the environment, to the extent they may be adversely affected by the project proposed in the application.

### **§ 52h.9 What matters must be reviewed for unsolicited contract proposals?**

(a) Except as otherwise provided by law, no awarding official shall award a contract based upon an unsolicited contract proposal covered by this part unless the proposal 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 proposal.

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

### **§ 52h.10 What matters must be reviewed for solicited contract proposals?**

(a) Subject to paragraphs (b) and (c) of this section, no awarding official shall issue a request for contract proposals with respect to a contract project involving solicited contract proposals, unless the project concept has been reviewed by a peer review group or advisory council in accordance with this part and the group has made recommendations concerning the scientific merit of the concept.

(b) The awarding official may delay carrying out the requirements for peer review of paragraph (a) of this section until after issuing a request for proposals if the official determines that the accomplishment of essential program objectives would otherwise be placed in jeopardy and any further delay clearly would not be in the best

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interest of the Government. The awarding official shall specify in writing the grounds on which this determination is based. Under these circumstances, the awarding official will not award a contract until peer review of the project concept and the proposals has been completed. The request for proposals shall state that the project concept will be reviewed by a peer review group and that no award will be made until the review is conducted and recommendations made based on that review.

(c) The awarding official may determine that peer review of the project concept for behavioral or biomedical research and development contracts is not needed if one of the following circumstances applies: the solicitation is to re-compete or extend a project that is within the scope of a current project that has been peer reviewed, or there is a Congressional authorization or mandate to conduct specific contract projects. If a substantial amount of time has passed since the concept review, the awarding official shall determine whether peer review is required to ensure the continued scientific merit of the concept.

(d) Except to the extent otherwise provided by law, the recommendations referred to in this section are advisory only and not binding on the awarding official.

### **§ 52h.11 What are the review criteria for contract projects and proposals?**

(a) In carrying out its review of a project concept under § 52h.10(a) or § 52h.10(b), the peer review group shall take into account, among other pertinent factors:

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

(2) The availability of the technology and other resources necessary to achieve those goals;

(3) The extent to which there are identified, practical uses for the anticipated results of the activity; and

(4) Where the review includes the project approach, the adequacy of the methodology to be utilized in carrying out the activity.