

§ 52h.4

42 CFR Ch. I (10–1–03 Edition)

Human Services (45 CFR part 11), implementing regulations and chapter 9 of the Department of Health and Human Services General Administration Manual¹ will govern the establishment and operation of peer review groups, including that meetings shall be open to the public except as determined by the Secretary.

(b) Subject to § 52h.5 and paragraph (a) of this section, the Director of the National Institutes of Health, the Administrator of the Alcohol, Drug Abuse and Mental Health Administration, and the Administrator of the Health Resources and Services Administration will adopt procedures for the conduct of reviews and the formulation of recommendations under §§ 52h.7, 52h.9 and 52h.10 within their respective agencies.

(Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 475, 88 Stat. 360, 89 Stat. 351, 92 Stat. 3436 (42 U.S.C. 289f-4))

[43 FR 7862, Feb. 24, 1978, as amended at 45 FR 35328, May 27, 1980; 49 FR 38111, Sept. 27, 1984]

§ 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 will be governed by Chapter 9 of the Department of Health and Human Services General Administration Manual.¹

(b) Subject to paragraph (a) of this section, members will be selected based upon their training and experience in relevant scientific or technical fields, 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 such research;

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

(3) Recognition as reflected by awards and other honors received from scientific and professional organizations outside the Department of Health and Human Services; 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.

(c) Not more than one-fourth of the members of any peer review group to which these regulations are applicable may be officers or employees of the United States. For purposes of the preceding sentence, membership on such groups does not make an individual an officer or employee of the United States.

§ 52h.5 Conflict of interest.

(a) Members of peer review groups covered by this part are subject to relevant provisions in title 18 of the United States Code, relating to criminal activity, the Department of Health and Human Services Standards of Conduct (45 CFR part 73), and Executive Order 11222, as amended.

(b) In addition to any restrictions imposed under paragraph (a) of this section:

(1) No member of a peer review group may participate in or be present during any review by said group of a grant application, contract project, or contract proposal in which, to the member's knowledge, any of the following has a financial interest: (i) The member or his or her spouse, parent, child, or partner, (ii) any organization in which the member or his or her spouse, parent, child, or partner is serving as an officer, director, trustee, partner, or employee, or is otherwise similarly associated, or (iii) any organization with which the member or his or her spouse, parent, child, or partner is negotiating or has any arrangement concerning prospective employment or other similar association.

(2) In the event any member of a peer review group or his or her spouse, parent, child, or partner is currently or expected to be the principal investigator or member of the staff responsible for carrying out any research or development activities contemplated as part of a grant application, contract

project, or contract proposal, that group is disqualified and the review will be conducted by another group with the expertise to do so. If there is no other group with the requisite expertise, the review will be conducted by an ad hoc group no more than 50 percent of whose members may be from the disqualified group. The composition of any such ad hoc group will be determined in accordance with § 52h.4(b) and § 52h.4(c) of this part and, to the extent feasible, § 52h.4(a) of this part.

(3) Where a member of a peer review group participates in or is present during:

(i) Development or review of a project approach or request for proposals by said group or

(ii) Review by said group under § 52h.10(b) or § 52h.10(c), i.e. after the issuance of a request for proposals, no contract may thereafter be awarded as the result of such development or review to said member, his or her spouse, parent, child, or partner or any organization in which the member, his or her spouse, parent, child, or partner was serving as officer, director, trustee, partner, or employee at the time of such development or review or with which the member, his or her spouse, parent, child, or partner was negotiating or had any arrangement concerning prospective employment at said time.

(4) No member of a peer review group may participate in any review under this part 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 preaward or postaward) as an officer or employee of the United States.

(c) Where permissible under the statutes, standards, and order cited in paragraph (a) of this section, the Director of the National Institutes of Health, the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration, the Administrator of the Health Resources and Services Administration, or their designees may waive the requirements in paragraph (b) of this section if he or she determines that there is no other practical means for securing appropriate expert

advice on a particular grant application, contract project, or contract proposal.

(Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 475, 88 Stat. 360, 89 Stat. 315, 92 Stat. 3436 (42 U.S.C. 289L-4))

[43 FR 7862, Feb. 24, 1978, as amended at 45 FR 35328, May 27, 1980; 49 FR 38111, Sept. 27, 1984]

§ 52h.6 Availability of information.

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 in the Freedom of Information Act (5 U.S.C. 552), the Federal Advisory Committee Act (5 U.S.C. App. I), the Privacy Act (5 U.S.C. 552a), and implementing Department of Health and Human Services regulations (45 CFR parts 5, 5b).

§ 52h.7 Grants; matters to be reviewed.

(a) No awarding official will make 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 said group has made recommendations concerning the scientific merit of such application. In addition, where under applicable law an awarding official is required to secure the approval or advice of a national advisory council or board concerning an application, said application will not be considered by the council or board unless it has been reviewed by a peer review group in accordance with the provisions of this part and said 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 for by law, such recommendations are advisory only and not binding on the awarding official or national advisory council or board.

§ 52h.8 Grants; review criteria.

In carrying out its review under § 52h.7, the peer review group will take into account, among other factors:

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