

**§ 52e.9 Additional conditions.**

The Director, may with respect to any grant award impose additional conditions prior to or at the time of any award when in the Director's judgment those conditions are necessary to assure or protect advancement of the approved project, the interests of the public health, or the conservation of grant funds.

[45 FR 12249, Feb. 25, 1980, as amended at 58 FR 54299, Oct. 21, 1993]

**PART 52h—SCIENTIFIC PEER REVIEW OF RESEARCH GRANT APPLICATIONS AND RESEARCH AND DEVELOPMENT CONTRACT PROJECTS**

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AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 475, 88 Stat. 360, 89 Stat. 351 (42 U.S.C. 289f–4); sec. 955(a), Pub. L. 97–35, 95 Stat. 590 (42 U.S.C. 300z–7(e)).

SOURCE: 43 FR 7862, Feb. 24, 1978, unless otherwise noted.

**§ 52h.1 Applicability.**

The regulations in this part apply to:

(a) Applications for grants for biomedical and behavioral research, under the Act to the National Institutes of Health; the Alcohol, Drug Abuse, and Mental Health Administration; or any of their components; or the Division of Nursing, Bureau of Health Professions, Health Resources and Services Administration. These regulations do not apply to applications for:

(1) Continuation funding for budget periods within an approved project period;

(2) Supplemental funding to meet increased administrative costs within a project period; or

(3) Construction grants.

(b) Biomedical and behavioral research and development contract projects administered by the National Institutes of Health; the Alcohol, Drug Abuse, and Mental Health Administration; or any of their components; or the Division of Nursing, Bureau of Health Professions, Health Resources and Services Administration.

(c) Applications for grants and contracts under section 2008 of the Act.

(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))

[45 FR 35328, May 27, 1980, as amended at 47 FR 50261, Nov. 5, 1982; 49 FR 38111, Sept. 27, 1984]

**§ 52h.2 Definitions.**

As used in this part:

(a) *Act* means the Public Health Service Act, as amended.

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

(c) *Budget period* means the interval of time (usually 12 months) into which the project period is divided for budgetary and reporting purposes.

(d) *Awarding official* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated; *Except that*, where the Act specifically authorizes another official to make awards in connection with a particular program, the "awarding official" shall mean said other official and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(e) *Peer review group* means a group of experts qualified by training and experience in particular scientific or technical fields to give expert advice, in accordance with the provisions of this part, on the scientific and technical merit of grant applications or contract projects in those fields.

(f) *Research* means systematic study directed toward new or fuller knowledge and understanding of the subject studied.

(g) *Development* means the systematic use of knowledge and understanding gained from research, directed toward creating useful materials, devices, systems, or methods.

(h) *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 of a subject and/or to use such knowledge and understanding to develop useful materials, devices, systems, or methods. The terms include (but are not limited to) development and utilization of resources, testing, demonstrations, clinical trials, preparation of reports, and production of experimental or test models necessary or incidental to a research and/or development activity, but exclude quantity production and routine product testing and quality control.

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

(j) *Project approach* means the methodology to be followed and the resources needed in carrying out the project.

(k) *Contract proposal* means a written offer to enter into a contract, submitted to an awarding official by an individual or non-Federal organization, and including as a minimum a description of the nature, purpose, duration, and cost of the project and the methods, personnel, and facilities to be utilized in carrying it out.

(l) *Solicited contract proposal* has the same meaning as in 41 CFR 3-1.353(b)(2).

(m) *Unsolicited contract proposal* has the same meaning as in 41 CFR 3-4.5201.

(n) *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 competitive 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.

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

(a) To the extent applicable, the Federal Advisory Committee Act (5 U.S.C. App. I), Department of Health and Human Services (45 CFR part 11), implementing regulations and chapter 9 of the Department of Health and Human Services General Administration Manual<sup>1</sup> 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. 289-4))

[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.<sup>1</sup>

(b) Subject to paragraph (a) of this section, members will be selected based upon their training and experience in

<sup>1</sup>The 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.

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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;

(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. 289f-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;

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

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

(d) The reasonable availability of resources necessary to the research;

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

(f) Where an application involves activities which could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against or minimizing such effects.

#### § 52h.9 Unsolicited contract proposals; matters to be reviewed.

(a) No awarding official will 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 (pursuant to procedures set forth in 41 CFR subpart 3-4.52) and said group has made recommendations concerning the scientific merit of such proposal.

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

#### § 52h.10 Contract projects involving solicited contract proposals; matters to be reviewed.

(a) Subject to paragraph (b) of this section, no awarding official will 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 in accordance with the provisions of this part and said

group has made recommendations concerning the scientific merit of said concept. Where in the judgment of the awarding official the project approach has been sufficiently well defined by the time the review required by the preceding sentence is conducted, this review and the resulting recommendations shall include the project approach as well.

(b) The awarding official may waive the requirements of paragraph (a) of this section for peer review before issuing a request for contract proposals if he determines that the accomplishments of essential program objectives would otherwise be placed in jeopardy and any further delay would clearly not be in the best interest of the Government. The awarding official shall specify in writing the grounds on which this determination is based. Under such circumstances, the awarding official will not award a contract based on the request for contract proposals unless the proposals received in response to the request have been reviewed by a peer review group and that group has made recommendations concerning the scientific merit of the project concept and of the approaches outlined in the proposals. The request for proposals will indicate that the project concept has not been reviewed by a peer review group and that no award will be made until such review is conducted and recommendations made based on such review.

(c) 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 Service Administration, or their designees may identify individual contracts or classes of contracts which may not be awarded unless all pertinent contract proposals have been reviewed by a peer review group in accordance with the provisions of this part and that group has made recommendations concerning the scientific merit of the proposals.

(d) Except to the extent otherwise provided for by law, such recommenda-

tions are advisory only and not binding on the awarding official.

(Sec. 215, Public Health Service Act, 58 Stat. 690, as amended (42 U.S.C. 216); sec. 475, Public Health Service Act, 88 Stat. 360, 89 Stat. 351, 92 Stat. 3436 (42 U.S.C. 2891-4); sec. 955(a), Pub. L. 97-35, 95 Stat. 590 (42 U.S.C. 300z-7(e)))

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

**§ 52h.11 Contract projects and proposals; review criteria.**

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

(b) In carrying out its review of unsolicited contract proposals under § 52h.9, the peer review group will take into account, among other factors, those criteria in § 52h.8 which are relevant to the particular proposals.

(c) In carrying out its review of solicited contract proposals under § 52h.10(c) the peer review group will evaluate each proposal in accordance with the criteria set forth in the request for proposals.

**§ 52h.12 Applicability of other regulations.**

The regulations in this part are in addition to, and do not supersede other regulations concerning grant applications, contract projects, or contract proposals appearing elsewhere in this title, title 41, or title 45 of the Code of Federal Regulations.