

Public Health Service, HHS

§ 52h.2

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

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

52h.12 Applicability of other regulations.

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.

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(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 Manual¹ will govern the establishment and operation of peer review groups, including that meetings shall

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.

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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;

(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