

Public Health Service, HHS

§ 52h.2

45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to State and local governments

45 CFR part 93—New restrictions on lobbying
51 FR 16958 or successor—NIH Guidelines for Research Involving Recombinant DNA Molecules

“Public Health Service Policy on Humane Care and Use of Laboratory Animals,” Office for Protection from Research Risks, NIH (Revised September 1986), or successor
59 FR 14508 (as republished March 28, 1994), as may be amended, or its successor—NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research.

[58 FR 54298, Oct. 21, 1993, as amended at 59 FR 59372, Nov. 17, 1994]

§ 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: 42 U.S.C. 216; 42 U.S.C. 282 (b)(6); 42 U.S.C. 284 (c)(3); 42 U.S.C. 289a.

SOURCE: 69 FR 275, Jan. 5, 2004, unless otherwise noted.

§ 52h.1 Applicability.

(a) This part applies to:

(1) Applications of the National Institutes of Health for grants or cooperative agreements (a reference in this part to grants includes cooperative agreements) for biomedical and behavioral research; and

(2) Biomedical and behavioral research and development contract project concepts and proposals for contract projects administered by the National Institutes of Health.

(b) This part does 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.

§ 52h.2 Definitions.

As used in this part:

(a) *Act* means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*).

(b) *Appearance of a conflict of interest* means that a reviewer or close relative or professional associate of the reviewer has a financial or other interest in an application or proposal that is known to the reviewer or the government official managing the review and would cause a reasonable person to question the reviewer’s impartiality if he or she were to participate in the review; the government official managing the review (the Scientific Review Administrator or equivalent) will evaluate the appearance of a conflict of interest and determine, in accordance with this subpart, whether or not the interest would likely bias the reviewer’s evaluation of the application or proposal.

(c) *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 that official and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

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

(e) *Close relative* means a parent, spouse, domestic partner, or son or daughter.

(f) *Contract proposal* means a written offer to enter into a contract that is submitted to the appropriate agency official by an individual or nonfederal organization which includes, at 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. A contract proposal may be unsolicited by the federal government or submitted in response to a request for proposals.

(g) *Development* means the systematic use of knowledge gained from research to create useful materials, devices, systems, or methods.

(h) *DHHS* means the Department of Health and Human Services.

(i) *Director* means the Director of the National Institutes of Health and any other official or employee of the National Institutes of Health to whom the authority involved has been delegated.

(j) *Grant* as used in this part, includes cooperative agreements.

(k) *Peer review group* means a group of primarily nongovernment experts qualified by training and experience in particular scientific or technical fields, or as authorities knowledgeable in the various disciplines and fields related to the scientific areas under review, to give expert advice on the scientific and technical merit of grant applications or contract proposals, or the concept of contract projects, in accordance with this part.

(l) *Principal investigator* has the same meaning as in 42 CFR part 52.

(m) *Professional associate* means any colleague, scientific mentor, or student with whom the peer reviewer is currently conducting research or other significant professional activities or with whom the member has conducted such activities within three years of the date of the review.

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

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

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

(q) *Real conflict of interest* means a reviewer or a close relative or professional associate of the reviewer has a financial or other interest in an application or proposal that is known to the reviewer and is likely to bias the reviewer's evaluation of that application or proposal as determined by the government official managing the review (the Scientific Review Administrator, or equivalent), as acknowledged by the reviewer, or as prescribed by this part. A reviewer shall have a real conflict of interest if he/she or a close relative or professional associate of the reviewer:

(1) Has received or could receive a direct financial benefit of any amount deriving from an application or proposal under review;

(2) Apart from any direct financial benefit deriving from an application or proposal under review, has received or could receive a financial benefit from the applicant institution, offeror or principal investigator that in the aggregate exceeds \$10,000 per year; this amount includes honoraria, fees, stock or other financial benefit, and additionally includes the current value of the reviewer's already existing stock holdings. The Director, NIH, may amend the dollar threshold periodically, as appropriate, after public notice and comment; or

(3) Has any other interest in the application or proposal that is likely to bias the reviewer's evaluation of that application or proposal. Regardless of the level of financial involvement or

other interest, if the reviewer feels unable to provide objective advice, he/she must recuse him/herself from the review of the application or proposal at issue. The peer review system relies on the professionalism of each reviewer to identify to the designated government official any real or apparent conflicts of interest that are likely to bias the reviewer's evaluation of an application or proposal.

(r) *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 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.

(s) *Research* has the same meaning as in 42 CFR part 52.

(t) *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 in the areas of biomedical or behavioral research and/or to use such knowledge and understanding to develop useful materials, devices, systems, or methods.

(u) *Scientific review group* has the same meaning as peer review group, which is defined in paragraph (k) of this section.

(v) *Solicited contract proposal* has the same meaning as the definition of offer in 48 CFR 2.101.

(w) *Unsolicited contract proposal* has the same meaning as unsolicited proposal in 48 CFR 15.601.

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

(a) To the extent applicable, the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2) and

chapter 9 of the DHHS General Administration Manual¹ shall govern the establishment and operation of peer review groups.

(b) Subject to § 52h.5 and paragraph (a) of this section, the Director will adopt procedures for the conduct of reviews and the formulation of recommendations under §§ 52h.7, 52h.9, and 52h.10.

§ 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 shall be governed by chapter 9 of the DHHS General Administration Manual.

(b) Subject to paragraph (a) of this section, members will be selected based upon their training and experience in relevant scientific or technical fields, or upon their qualifications as authorities knowledgeable in the various disciplines and fields related to the scientific areas under review, 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 the research;

(3) Recognition as reflected by awards and other honors received from scientific and professional organizations; 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, or authorities knowledgeable in the various disciplines and fields related to the scientific areas under review.

(c) Except as otherwise provided by law, not more than one-fourth of the members of any peer review group to

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