

**§ 52d.9**

**§ 52d.9 Additional conditions.**

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

**PART 52e—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE GRANTS FOR PREVENTION AND CONTROL PROJECTS**

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AUTHORITY: 42 U.S.C. 216, 285b-1.

SOURCE: 45 FR 12249, Feb. 25, 1980, unless otherwise noted.

**§ 52e.1 To what programs do these regulations apply?**

(a) This part applies to grants under section 419 of the Act (42 U.S.C. 285b-1) for projects to:

- (1) Demonstrate and evaluate the effectiveness of new techniques or procedures for the prevention and control of heart, blood vessel, lung, and blood diseases, with special consideration given to the prevention and control of these diseases in children, and in populations that are at increased risk with respect to such diseases;
- (2) Develop and evaluate methods of educating health practitioners concerning the prevention and control of these diseases; and
- (3) Develop and evaluate methods of educating the public concerning the prevention and control of these diseases.

(b) For purposes of this part, prevention and control projects shall include community-based and population-based programs carried out in cooperation

with other Federal agencies, with public health agencies of State or local governments, with nonprofit private entities that are community-based health agencies, or with other appropriate public or nonprofit private entities.

[45 FR 12249, Feb. 25, 1980; 45 FR 20097, Mar. 27, 1980, as amended at 58 FR 54298, Oct. 21, 1993; 59 FR 59372, Nov. 17, 1994]

**§ 52e.2 Definitions.**

As used in this part:

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

*Council* means the National Heart, Lung, and Blood Advisory Council, established under section 406 of the Act (42 U.S.C. 284a).

*Director* means the Director of the National Heart, Lung, and Blood Institute and any official to whom the authority involved may be delegated.

*Emergency medical services* means the services utilized in responding to the perceived individual need for immediate medical care in order to prevent loss of life or aggravation of physiological or psychological illness or injury.

*HHS* means the Department of Health and Human Services.

*National program* means the National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program referred to in section 421 of the Act (42 U.S.C. 285b-3).

*Nonprofit* as applied to any agency or institution means an agency or institution which is a corporation or an association, no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

*PHS* means the Public Health Service.

[58 FR 54298, Oct. 21, 1993]

**§ 52e.3 Who is eligible to apply?**

To be eligible for a grant under this part, an applicant must be a public or nonprofit private agency or institution.

[45 FR 12249, Feb. 25, 1980, as amended at 58 FR 54298, Oct. 21, 1993]

**§ 52e.4 How to apply.**

(a) Application for a grant under this subpart shall be made on an authorized form.<sup>2</sup> Applicants shall submit completed forms on or before the dates the Director may prescribe.

(b) Each private institution which does not already have on file with the National Institutes of Health evidence of nonprofit status, must submit with its application acceptable proof of such status.

(c) In addition to any other pertinent information that the Director may require each application shall set forth in detail:

(1) The nature and purpose of the proposed project and the methods to be employed in carrying it out;

(2) The relevance of the proposed project to the National Program;

(3) The defined population to participate in the proposed project and the rationale for its selection;

(4) With respect to applications relating to projects covered by § 52e.1(a)(1), prior research findings on which the proposed project is based;

(5) The personnel, facilities, and other resources, including community resources, available to carry out the proposed project;

(6) Current activities of the applicant involving prevention or control of heart, blood vessel, lung, and blood diseases, the sources of funding for such activities, and the anticipated relationship of these activities to the proposed project;

(7) The names and qualifications of the project director and key staff members who would be responsible for conducting the proposed project;

(8) Proposed methods for monitoring and evaluating the project; and

(9) The proposed project period; a detailed budget for the first budget period, including a list of other anticipated sources of support and anticipated total needs for each of the succeeding budget periods of the requested

project period; and a justification for the amount of grant funds requested.

[45 FR 12249, Feb. 25, 1980, as amended at 58 FR 54298, Oct. 21, 1993]

**§ 52e.5 What are the project requirements?**

(a) An approvable application must demonstrate to the satisfaction of the Director that:

(1) With respect to applications relating to projects covered by § 52e.1(a)(1), the techniques or procedures to be demonstrated and evaluated have been found safe and effective in the research setting and, based upon research findings, appear to have the potential for general applicability to the prevention, diagnosis, or treatment of heart, blood vessel, lung, or blood diseases;

(2) With respect to applications relating to projects covered by § 52e.1(a)(2) and § 52e.1(a)(3), the project will include development and evaluation of one or more methods for educating health practitioners or the public concerning advances in the prevention, diagnosis, or treatment of such diseases; and

(3) The nature of the project is such that its completion may be anticipated within the project period, or such other period as may be specified in the application.

(b) The project must, in the judgment of the Director, be necessary for cooperation by the National Heart, Lung, and Blood Institute with one or more other Federal Health agencies, State, local or regional public health agencies, or nonprofit private health agencies in the diagnosis, prevention, or treatment of heart, blood vessel, lung or blood diseases.

[45 FR 12249, Feb. 25, 1980, as amended at 58 FR 54298 and 54299, Oct. 21, 1993]

**§ 52e.6 How will NIH evaluate applications?**

(a) Within the limits of funds available, after consultation with the Council, the Director may award grants to applicants with proposed projects which in the Director's judgment will best promote the purposes of section 419 of the Act, taking into consideration among other pertinent factors:

(1) The scientific and technical merit of the proposed project;

<sup>2</sup>Applications and instructions are available from the Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20205.

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(2) The significance of the project in relation to the goals of the National Program;

(3) Whether the project appropriately emphasizes the prevention, diagnosis, or treatment of heart, blood vessel, lung, or blood diseases of children;

(4) The qualifications and experience of the project director and other key personnel;

(5) The administrative and managerial capability and fiscal responsibility of the applicant;

(6) The reasonableness of the proposed budget in relation to the proposed project;

(7) The adequacy of the methods proposed for monitoring and evaluating the proposed project; and

(8) The degree to which the application adequately provides for the requirements set forth in §§ 52e.5(a) and 52e.5(b).

(b) The notice of grant award specifies how long HHS intends to support the project without requiring the project to re compete for funds. This period, called the project period, will usually be for 1–5 years.

(c) Generally, the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(d) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

(e) Any funds granted under this part shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, the regulations of this part, the terms, and conditions of

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the award, and the applicable cost principles prescribed in subpart Q of 45 CFR part 74.

[45 FR 12249, Feb. 25, 1980, as amended at 58 FR 54298, Oct. 21, 1993]

### § 52e.7 What are the terms and conditions of awards?

(a) Any funds granted pursuant to this part shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, the regulations of this part, the terms and conditions of the award, and the applicable cost principles prescribed by subpart Q of 45 CFR part 74.

(b) The Director may permit unobligated grant funds remaining in the grant account at the close of a budget period to be carried forward for obligation during a subsequent budget period, provided a continuation award is made for that period and the NHLBI Director's written approval is obtained. The amount of any subsequent award will take into consideration unobligated grant funds remaining in the grant account.

[45 FR 12249, Feb. 25, 1980, as amended at 58 FR 54298 and 54299, Oct. 21, 1993]

### § 52e.8 Other HHS regulations and policies that apply.

Several other regulations apply to grants under this part. These include but are not necessarily limited to:

42 CFR part 50, subpart A—Responsibility of PHS awardee and applicant institutions for dealing with and reporting possible misconduct in science

42 CFR part 50, subpart D—Public Health Service grant appeals procedure

45 CFR part 16—Procedures of the Departmental Grant Appeals Board

45 CFR part 46—Protection of human subjects

45 CFR part 74—Administration of grants

45 CFR part 75—Informal grant appeals procedures

45 CFR part 76—Governmentwide debarment and suspension (nonprocurement) and governmentwide requirements for drug-free workplace (grants)

45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—Effectuation of Title VI of the Civil Rights Act of 1964

45 CFR part 81—Practice and procedure for hearings under part 80 of this title

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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.