

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, 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;

(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 recompete 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 the award, and the applicable cost principles prescribed in 2 CFR parts 200 and 300, subpart E.

[45 FR 12249, Feb. 25, 1980, as amended at 58 FR 54298, Oct. 21, 1993; 81 FR 3008, Jan. 20, 2016; 89 FR 80066, Oct. 2, 2024]

§ 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

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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 2 CFR parts 200 and 300, subpart E.

(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, 54299, Oct. 21, 1993; 81 FR 3008, Jan. 20, 2016; 89 FR 80066, Oct. 2, 2024]

§ 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:

- 2 CFR parts 200 and 300—Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- 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 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
- 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 93—New restrictions on lobbying

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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; 81 FR 3008, Jan. 20, 2016; 89 FR 80066, Oct. 2, 2024]

§ 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

Sec.

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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: