

Council or other body as may be required by law, the Secretary will (1) approve, (2) defer because of either lack of funds or a need for further evaluation, or (3) disapprove support of the proposed project in whole or in part. With respect to approved projects, the Secretary will determine the project period (subject to extension as provided in § 52.7(c)) during which the project may be supported. Any deferral and disapproval of an application will not preclude its reconsideration or a re-application.

[45 FR 12240, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980]

§ 52.6 Grant awards.

(a) Within the limits of funds available for that purpose, the Secretary will award a grant to those applicants whose approved projects will in the Secretary's judgment best promote the purposes of the statute authorizing the grant and the regulations of this part. The date specified by the Secretary as the beginning of the project period shall be no later than 9 months following the date of any initial or new award statement unless the Secretary finds that because of the nature of a project or the grantee's particular circumstances earlier assurance of grant support is required to initiate the project. 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 subpart Q of 45 CFR part 74.

(b) *Evaluation of unapproved drug treatments for AIDS.* Grants under section 2314 of the Act to support research relating to the evaluation of drug treatments for AIDS not approved by the Commissioner of Food and Drugs, shall be subject to appropriate scientific and ethical guidelines established by the Secretary for each project, pursuant to section 2314(c) of the Act. In order to receive a grant, the applicant must agree to comply with those guidelines.

(c) *Notice of grant award.* (1) The notice of grant award specifies how long HHS intends to support the project

without requiring the project to compete for funds. This period, called the project period, will usually be for 1-5 years.

(2) 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 an application at the time and in the form and manner as the Secretary may prescribe to have support continued for each subsequent year.

(3) 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.

(d) *Multiple or concurrent awards.* Whenever a research project involves a number of different but related problems, activities or disciplines which require evaluation by different groups, or whenever support for a project could be more effectively administered by separate handling of separate aspects of the project, the Secretary may evaluate, approve, and make one or more awards pursuant to one or more applications. When making more than one award in response to a single application, the Secretary shall consult with the applicant organization(s), as appropriate.

(e) *Unobligated balances.* The Secretary 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 Secretary's written approval is obtained.

(f) *Award for continuation of project under new grantee.* The Secretary, upon application in accordance with the provisions of § 52.4 and without further action by a Council or other body, may make a grant to any institution or other person eligible under § 52.3 for continuation of a currently supported project for which a grant was previously made to another institution or person, provided the Secretary finds that the change in the conduct of the project is consonant with the previous

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evaluation and approval of the project under § 52.5.

[45 FR 12240, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980; 61 FR 55105, Oct. 24, 1996; 74 FR 57921, Nov. 10, 2009]

§ 52.7 Use of funds; changes.

(a) *Delegation of fiscal responsibility.* The grantee may not in whole or in part delegate or transfer to another person responsibility for the use or expenditure of grant funds.

(b) *Changes in project.* The permissible changes by the principal investigator in the approved project shall be limited to changes in methodology, approach or other aspects of the project to expedite achievement of the project's research objectives, including changes that grow out of the approved project and serve the best scientific strategy. If the grantee and the principal investigator are uncertain whether a change complies with this provision, the question must be referred to the Secretary for a final determination.

(c) *Changes in project period.* The project period determined pursuant to § 52.5(b) may be extended by the Secretary, with or without additional grant support, for such an additional period as the Secretary determines may be required to complete, or fulfill the purposes of, the approved project.

[45 FR 12240, Feb. 25, 1980]

§ 52.8 Other HHS regulations and policies that apply.

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

- 37 CFR part 401—Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements
- 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
- 42 CFR part 50, subpart F—Responsibility of applicants for promoting objectivity in research for which PHS funding is sought
- 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

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- 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
- 45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving 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
- 59 FR 14508 (March 28, 1994)—NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research.

NOTE: This policy is subject to changes, and interested persons should contact the Office of Research on Women's Health, NIH, Room 201, Building 1, MSC 0161, BETHESDA, MD 20892-0161 (301-402-1770; not a toll-free number) to obtain references to the current version and any amendments.]

- 59 FR 34496 (July 5, 1994)—NIH Guidelines for Research Involving Recombinant DNA Molecules.

NOTE: This policy is subject to changes, and interested persons should contact the Office of Recombinant DNA Activities, NIH, Suite 323, 6000 Executive Boulevard, MSC 7010, Bethesda, MD 20892-7010 (301-496-9838; not a toll-free number) to obtain references to the current version and any amendments.]

“PHS Grants Policy Statement,” DHHS Publication No. (OASH) 94-50,000 (Rev.) April 1, 1994.

NOTE: This policy is subject to changes, and interested persons should contact the Grants Policy Branch, OASH, Room 17A45, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857 (301-443-1874; not a toll-free number) to obtain references to the current version and any amendments.]

“Public Health Service Policy on Humane Care and Use of Laboratory Animals,” Office for Protection from Research Risks, NIH (Revised September 1986).