

the program services period, in accordance with 45 CFR 92.50(b),

(4) A financial status report, to be submitted within 90 days after the end of the program services period, in accordance with 45 CFR 92.50(b),

(5) Such additional reports as the Secretary may require.

(c) The following shall be specifically addressed in final program reports:

- (1) Description of services provided,
- (2) Number of individuals assisted,
- (3) Amount of funding expended and for what purposes,
- (4) Personnel costs,
- (5) Training costs,
- (6) Technical consultation costs,
- (7) Equipment costs,
- (8) Travel and transportation costs, and

(9) A narrative describing lessons learned and exemplary practices, and a description of the transition plan, for how services will be funded or provided when Federal funds have been exhausted.

PARTS 51e–51g [RESERVED]

PART 52—GRANTS FOR RESEARCH PROJECTS

Sec.

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AUTHORITY: 42 U.S.C. 216.

§ 52.1 To which programs do these regulations apply?

(a) *General.* The regulations of this part apply to all health-related research project grants administered by the PHS or its components, except for grants for health services research, demonstration, and evaluation projects administered by the Agency for Health Care Policy and Research. These regulations do not apply to research grants that are not for the support of an identified research project (sometimes re-

ferred to as general research support grants), grants for the construction or operation of research facilities, grants for prevention or educational programs, demonstration grants, traineeships, training grants, or to the support of research training under the National Research Service Awards program.

(b) *Specific programs covered.* From time to time the Secretary will publish a list of the research project grant programs covered by this part. The list is for informational purposes only and is not intended to restrict the statement of applicability in paragraph (a) of this section. In addition, information on particular research project grant programs, including applications and instructions, may be obtained from the component of the PHS that administers the program.

[61 FR 55105, Oct. 24, 1996.]

§ 52.2 Definitions.

As used in this part:

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

Grantee means the institution, organization, individual or other person designated in the grant award document as the responsible legal entity to whom a grant is awarded under this part. The term shall also mean the recipient of a cooperative agreement awarded under this part.

HHS means the Department of Health and Human Services.

Principal investigator means a single individual designated by the grantee in the grant application and approved by the Secretary, who is responsible for the scientific and technical direction of the project.

Project means the particular activity for which funding is sought under this part as described in the application for grant award.

Public Health Service and *PHS* means the operating division of the Department that consists of the Agency for Health Care Policy and Research, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, the Office of the Assistant Secretary for Health, the Substance

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Abuse and Mental Health Administration, and the Agency for Toxic Substances and Disease Registry.

Research means a systematic investigation, study or experiment designed to contribute to general knowledge relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanisms relating to, the biological functions, diseases, or related matters to be studied.

Secretary means the Secretary of HHS and any other officer or employee of the HHS to whom the authority involved may be delegated.

[61 FR 55105, Oct. 24, 1996]

§ 52.3 Who is eligible to apply for a grant?

(a) *Persons eligible.* Any individual, corporation, public or private institution or agency, or other legal entity shall be eligible for a grant award, except:

(1) An individual or entity which is otherwise ineligible for an award under applicable law or regulation;

(2) Federal agencies or institutions, unless specifically authorized by law to receive the grant; or

(3) Individuals, corporations, institutions, agencies, and other entities during the period they are debarred or suspended from eligibility for Federal financial assistance (see 45 CFR part 76).

(b) *Permissible activities within research projects.* Any project found by the Secretary to be a research project within the meaning of this part shall be eligible for a grant award. Eligible projects may consist of laboratory, clinical, population, field, statistical, basic, applied or other types of investigations, studies or experiments, or combinations thereof, and may either be limited to one, or a particular aspect of a problem or subject, or may consist of two or more related problems or subjects for concurrent or consecutive investigation and involving multiple disciplines, facilities and resources.

(c) *Preferences.* In the award of grants for international research relating to the development and evaluation of vaccines and treatments for AIDS under section 2315 of the Act, preference shall be given to:

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(1) Activities conducted by, or in cooperation with, the World Health Organization, and

(2) With respect to activities in the Western Hemisphere, activities conducted by, or in cooperation with, the Pan American Health Organization or the World Health Organization.

[61 FR 55105, Oct. 24, 1996]

§ 52.4 How to apply for a grant.

Each institution interested in applying for a grant under this part must submit an application at such time and in such form and manner as the Secretary may prescribe.

[61 FR 55105, Oct. 24, 1996]

§ 52.5 Evaluation and disposition of applications.

(a) *Evaluation.* All applications filed in accordance with § 52.4 shall be evaluated by the Secretary through such officers and employees and such experts or consultants engaged for this purpose as the Secretary determines are specially qualified in the areas of research involved in the project, including review by an appropriate National Advisory Council or other body as may be required by law. The Secretary's evaluation shall take into account among other pertinent factors the scientific merit and significance of the project, the competency of the proposed staff in relation to the type of research involved, the feasibility of the project, the likelihood of its producing meaningful results, the proposed project period, and the adequacy of the applicant's resources available for the project and the amount of grant funds necessary for completion, and in the case of applications for support of research in emergency medical services, special consideration shall be given to applications for grants for research relating to the delivery of emergency medical services in rural areas.

(b) *Disposition.* On the basis of the Secretary's evaluation of an application in accordance with paragraph (a) of this section and subject to approvals, recommendations or consultations by the appropriate National Advisory 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 awards pursuant to two or more concurrent applications, each dealing with one or more specified aspects of the project.

(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 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]

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§ 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 objectively 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
- 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).

NOTE: This policy is subject to changes, and interested persons should contact the Office for Protection from Research Risks, NIH, Suite 3B01, 6100 Executive Boulevard, MSC 7507, Rockville, MD 20852-7507 (301-496-

7005; not a toll-free number) to obtain references to the current version and any amendments.]

[61 FR 55106 Oct. 24, 1996]

§ 52.9 Additional conditions.

The Secretary may with respect to any grant award or class of awards impose additional conditions prior to or at the time of any award when in the Secretary's judgment such 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 12240, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980]

PART 52a—NATIONAL INSTITUTES OF HEALTH CENTER GRANTS

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AUTHORITY: 42 U.S.C. 216, 284g, 285a-6(c)(1)(E), 285a-7(c)(1)(G), 285b-4, 285c-5, 285c-8, 285d-6, 285e-2, 285e-3, 285e-10a, 285f-1, 285g-5, 285g-7, 285g-9, 285m-3, 285o-2, 286a-7(c)(1)(G), 287c-32(c), 300cc-16.

SOURCE: 57 FR 61006, Dec. 23, 1992, unless otherwise noted.

§ 52a.1 To which programs do these regulations apply?

(a) The regulations of this part apply to grants by the National Institutes of Health and its organizational components to support the planning, establishment, expansion, and operation of research and demonstration and/or multipurpose centers in health fields described in this paragraph. Specifically, these regulations apply to:

(1) National Institute of Mental Health centers of excellence with respect to research on autism, as authorized by section 409C of the Act (42 U.S.C. 284g);

(2) National cancer research and demonstration centers (including payments for construction), as authorized by section 414 of the Act (42 U.S.C. 285a-3);

(3) National cancer research and demonstration centers with respect to breast cancer, as authorized by section 417 of the Act (42 U.S.C. 285a-6);

(4) National cancer and demonstration centers with respect to prostate cancer, as authorized by section 417A of the Act (42 U.S.C. 285a-7);

(5) National research and demonstration centers for heart, blood vessel, lung, and blood diseases, sickle cell anemia, blood resources, and pediatric cardiovascular diseases (including payments for construction), as authorized by section 422 of the Act (42 U.S.C. 485b-4);

(6) Research and training centers (including diabetes mellitus, and digestive, endocrine, metabolic, kidney and urologic diseases), as authorized by section 431 of the Act (42 U.S.C. 285c-5);

(7) Research and training centers regarding nutritional disorders, as authorized by section 434 of the Act (42 U.S.C. 285c-8);

(8) Multipurpose arthritis and musculoskeletal diseases centers (including payments for alteration, but not construction), as authorized by section 441 of the Act (42 U.S.C. 285d-6);

(9) Alzheimer's disease centers, as authorized by section 445 of the Act (42 U.S.C. 285e-2);

(10) Claude D. Peppers Older Americans Independence Centers, as authorized by section 445A of the Act (42 U.S.C. 285e-3);

(11) Centers of excellence in Alzheimer's disease research and treatment, as authorized by section 445I of the Act (42 U.S.C. 285e-10a);

(12) Research centers regarding chronic fatigue syndrome, as authorized by section 447 of the Act (42 U.S.C. 285f-1);

(13) Research centers with respect to contraception and infertility, as authorized by section 452A of the Act (42 U.S.C. 285g-5);

(14) Child health research centers, as authorized by section 452C of the Act (42 U.S.C. 285g-7);

(15) Fragile X research centers, as authorized by 452E of the Act (42 U.S.C. 285g-9);