

Secretary finds such principal amounts and interest rates to be reasonable.

[41 FR 5700, Dec. 30, 1976]

§ 51c.507 Facility which has previously received Federal grant.

No grant for the acquisition of a facility which has previously received a Federal grant for construction, acquisition, or equipment shall serve either to reduce or restrict the liability of the applicant or any other transferor or transferee from any obligation of accountability imposed by the Federal Government by reason of such prior grant.

[41 FR 5700, Dec. 30, 1976]

PARTS 51d—51g [RESERVED]

PART 52—GRANTS FOR RESEARCH PROJECTS

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AUTHORITY: Sec. 215, 58 Stat. 690, as amended, 63 Stat. 835 (42 U.S.C. 216); sec. 301, 58 Stat. 691, as amended, 60 Stat. 423, 62 Stat. 467, 601, 1017, 70 Stat. 490, 74 Stat. 1053, 85 Stat. 785, 86 Stat. 687, 88 Stat. 346, 360 (42 U.S.C. 241); sec. 303, 70 Stat. 929, as amended, 84 Stat. 1241, 88 Stat. 132, 346 (42 U.S.C. 242a); sec. 356, 82 Stat. 1174 (42 U.S.C. 263d); sec. 394, 79 Stat. 1062, as amended, 84 Stat. 63, 64, 66, 67, 87 Stat. 92, 88 Stat. 372 (42 U.S.C. 280b-5); sec. 1004, 89 Stat. 306, 352, as amended, 91 Stat. 389 (42 U.S.C. 300a-2); sec. 1006, 89 Stat. 308 (42 U.S.C. 300a-4); sec. 501, 90 Stat. 1038 (42 U.S.C. 4585); sec. 1205, 87 Stat. 597 (42 U.S.C. 300d-4); sec. 410, 68 Stat. 84, as amended, 90 Stat. 247, 90 Stat. 1040 (21 U.S.C. 1177); sec. 309(b), 92 Stat. 3447 (42 U.S.C. 242n); sec. 955(a), Pub. L. 97-35, 95 Stat. 589 (42 U.S.C. 300z-7(a)(1)).

§ 52.1 To which programs do these regulations apply?

(a) The regulations of this part apply to grants for the support of health-related research projects in programs relating to:

(1) The cause, diagnosis, treatment, control, or prevention of the physical or mental diseases, injuries, or impairments to human life, as authorized by sections 301, 303, and related provisions of the Act (42 U.S.C. 241, 242a);

(2) Electronic product radiation control programs designed to protect the public, and safety from electronic product radiation, as authorized by section 356 of the Act (42 U.S.C. 263d);

(3) Medical library science and related activities, and for the development or dissemination of new knowledge, techniques, systems, and equipment for processing, storing, retrieving, and distributing information pertaining to health sciences, as authorized by section 394 of the Act (42 U.S.C. 280b-5);

(4) Emergency medical techniques, methods, devices, and delivery, as authorized by section 1205 of the Act (42 U.S.C. 300d-4);

(5) The behavioral and biomedical etiology, treatment, mental and physical health consequences, and social and economic consequences, of alcohol abuse and alcoholism, as authorized by section 501 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4585);

(6) The improvement of drug maintenance techniques or programs, as authorized by section 410 of the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1177);

(7) Research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population, as authorized under section 1004 of the Act; and

(8) Health care technology assessments, including studies of the safety, efficacy, effectiveness, and cost effectiveness of particular technologies, their social, ethical, and economic impacts, as well as studies of methods of dissemination of information about technologies, and factors affecting the use of technologies as authorized by section 309(b) of the Act (42 U.S.C. 242n).

(9) Research on the causes, consequences and approaches to coping

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with adolescent sexual relations, contraceptive use, pregnancy and parenthood authorized by section 2008 of the Act.

(b) These regulations do not apply to general research support grants, grants for the construction of research facilities (see part 57 of this chapter), for the construction of hospital or other medical facilities (see part 53 of this chapter), or the award of fellowships (see part 61 of this chapter), traineeships (see part 63 of this chapter), training grants (see part 64 of this chapter), or to the support of research training under the National Research Service Awards program (see part 66 of this chapter).

[45 FR 12240, Feb. 25, 1980; 45 FR 20096, Mar. 27, 1980, as amended at 46 FR 4919, Jan. 19, 1981; 47 FR 50261, Nov. 5, 1982]

§ 52.2 Definitions.

As used in this part:

(a) *Secretary* 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 may be delegated.

(b) *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.

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

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

(e) *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.

(f) *Research project grant* means the award by the Secretary of funds to a grantee to assist in meeting the costs of conducting for the benefit of the public health an identified project which is intended and designed to establish, discover, develop, elucidate or confirm information or the underlying mechanisms relating to a program set forth in § 52.1.

(g) *Project* means the particular activity within the scope of one or more of the programs set forth in § 52.1 which

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is supported by a grant award under this part.

[45 FR 12240, Feb. 25, 1980]

§ 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, and

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

(3) Any individual, corporation, institution, agency or other entity that, having previously received a grant award, has failed willfully and materially in the judgment of the Secretary to comply with accounting or other requirements applicable to that prior award. Ineligibility for a grant award under this paragraph continues until terminated in the public interest by the Secretary.

(b) *Permissible activities within projects.* Any project found by the Secretary to be a research project within the meaning of § 52.1 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.

[45 FR 12240, Feb. 25, 1980, as amended at 46 FR 58675, Dec. 3, 1981]

§ 52.4 How to apply for a grant.

A grant application must include the following information:

(a) Nature requested project period, purpose and plan of the project;

(b) Name and qualifications of the principal investigator and any other key personnel;

(c) Qualifications of the principal staff members to be responsible for the project;

(d) The total facilities and resources that will be available;

(e) Justification of the amount of grant funds requested; and

(f) Other pertinent information the Secretary may require to evaluate the proposed project.

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

§ 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) *General.* Within the limits of funds available for such purpose, the Secretary shall award a grant to those applicants whose approved projects will in the Secretary's judgment best promote the purposes of § 52.1. 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) *Notice of grant award.* (1) 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.

(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 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.

(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.

(c) *Multiple, concurrent, initial 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 and approve two or more concurrent applications each dealing with one or more specified aspects of the project, and the Secretary may make two or more concurrent grant awards with respect to such a project.

(d) *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.

(e) *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]

§ 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 that apply.

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

- 42 CFR part 50, subpart D—Public Health Service grant appeals procedure
 - 45 CFR parts 6 and 8—Inventions and patents
 - 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 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
 - 48 FR 24556—Guidelines for Research Involving Recombinant DNA Molecules, published by the National Institutes of Health
- [49 FR 38110, Sept. 27, 1984]

§ 52.9 Other 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

Sec.

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

52a.2 Definitions.

52a.3 Who is eligible to apply?

52a.4 What information must each application contain?

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52a.7 For what purposes may a grantee spend grant funds?

52a.8 Other HHS regulations that apply.

52a.9 Additional conditions.

AUTHORITY: 42 U.S.C. 216, 285a-3, 285b-4, 285c-5, 285d-6, 285e-2, 285e-3, 285m-3, and 300cc-16.

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

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

(a) This part applies to grants by the National Institutes of Health and its organizational components to support the planning, establishment, expansion and operation of research and demonstration, multipurpose, and other centers. Specifically, this part applies to National Cancer Research and Demonstration Centers (including payments for construction), as authorized by section 414 of the Act; National Research and Demonstration Centers for Heart, Blood Vessel, Lung, and Blood Diseases, Sickle Cell Anemia, and Blood Resources (including payments for construction), as authorized by section 422 of the Act; Research and Training Centers (including diabetes mellitus, and digestive, endocrine, metabolic, kidney and urologic diseases), as authorized by section 431 of the Act; Multipurpose Arthritis and Musculoskeletal Disease Centers (including payments for alteration, but not construction), as authorized by section 441 of the Act; Alzheimer's Disease Centers, as authorized by section 445 of the Act; Claude D. Pepper Older Americans Independence Centers, as author-

ized by section 445A of the Act; Multipurpose Deafness and Other Communication Disorders Centers, as authorized by section 464C of the Act; and Centers for Acquired Immunodeficiency Syndrome Research, as authorized by section 2316 of the Act.

This part does not apply to:

(1) Grants for construction (see 42 CFR part 52b), except as noted above;

(2) Grants covered by 42 CFR part 52 (grants for research projects); or

(3) Grants for general research support under section 301(a)(3) of the Act (42 U.S.C. 241(a)(3)).

(b) This part also applies to cooperative agreements made to support the centers specified in paragraph (a) of this section. When a reference is made in this part to "grants," the reference shall include "cooperative agreements."

§ 52a.2 Definitions.

As used in this part:

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

Center means:

(1) For purposes of grants authorized in section 414 of the Act, an agency or institution which provides for planning and conducting basic and clinical research into, training in, and demonstration of advanced diagnostic, control, prevention and treatment methods for cancer;

(2) For purposes of grants authorized in section 422 of the Act, an agency or institution which provides for planning and basic and clinical research into, training in, and demonstration of, management of blood resources and advanced diagnostic, prevention, and treatment methods (including emergency medical services) for heart, blood vessel, lung, or blood diseases, including sickle cell anemia;

(3) For purposes of grants authorized in section 431 of the Act, a single institution or a consortium of cooperating institutions, which conducts research, training, information programs, epidemiological studies, data collection activities, and development of model programs in diabetes mellitus and related endocrine and metabolic diseases;

(4) For purposes of grants authorized in section 441 of the Act, a facility