§ 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:

2 CFR parts 200 and 300—Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.

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 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 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, as amended at 81 FR 3007, Jan. 20, 2016; 89 FR 80065, Oct. 2, 2024]

§ 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

Sec.

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);

(16) Multipurpose deafness and other communication disorders centers, as authorized by section 464C of the Act (42 U.S.C. 285m–3);

(17) National drug abuse research centers, as authorized by section 464N of the Act (42 U.S.C. 285o–2);

(18) Centers of excellence in biomedical and behavioral research training for individuals who are members of minority health disparity populations or other health disparity populations, as authorized by section 485F of the Act (42 U.S.C. 287c–32); and

(19) Centers for acquired immunodeficiency syndrome (AIDS) research, as authorized by section 2316 of the Act (42 U.S.C. 300cc–16).

(b) This part does not apply to:

(1) Grants for construction (see 42 CFR part 52b), except as noted in paragraph (a) of this section;

(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)).

(c) 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.''

[61 FR 55108, Oct. 24, 1996, as amended at 68 FR 69621, Dec. 15, 2003]

§ 52a.2 Definitions.

As used in this part:

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

Center means:

(a) For purposes of grants authorized by section 409C of the Act, a public or nonprofit private entity which provides for planning and conducting basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of autism, including the fields of developmental neurobiology, genetics, and psychopharmacology;

(b) For purposes of grants authorized by 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;

(c) For purposes of grants authorized by section 417 of the Act, an agency or institution which provides for planning and conducting basic, clinical, epidemiological, psychological, prevention and treatment research and related activities on breast cancer;

(d) For purposes of grants authorized by section 417A of the Act, an agency or institution which provides for planning and conducting basic, clinical, and epidemiological, psychosocial, prevention and control, treatment, research, and related activities on prostate cancer;

(e) For purposes of grants authorized by 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 services) for heart, blood vessel, lung, or blood diseases including sickle cell anemia;

(f) For purposes of grants authorized by 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;

(g) For purposes of grants authorized by section 434 of the Act, a single institution or a consortium of cooperating institutions which conducts basic and clinical research, training, and information programs in nutritional disorders, including obesity;

(h) For purposes of grants authorized by section 441 of the Act, a facility which conducts basic and clinical research into arthritis and musculosketal diseases; and orthopedic procedures, training, and information programs for the health community and the general public;

(i) For purposes of grants authorized by section 445 of the Act, a public or private nonprofit entity (including university medical centers) which conducts basic and clinical research (including multidisciplinary research) into, training in, and demonstration of advanced diagnostic, prevention, and treatment methods for Alzheimer's disease;

(j) For purposes of grants authorized by section 445A of the Act, a single public or private nonprofit institution or entity or a consortium of cooperating institutions or entities which conducts research into the aging processes and into the diagnosis and treatment of diseases, disorders, and complications related to aging, including menopause, which research includes research on such treatments, and on medical devices and other medical interventions regarding such diseases, disorders, and complications, that can assist individuals in avoiding institutionalization and prolonged hospitalization and in otherwise increasing the independence of the individuals.

(k) For the purposes of section 445I of the Act, a single institution or consortium of cooperating institutions which conducts basic and clinical research on Alzheimer's disease.

(l) For purposes of grants authorized by section 447 of the Act, a single institution or consortium of cooperating institutions which conducts basic and clinical research on chronic fatigue syndrome;

(m) For purposes of grants authorized by section 452A of the Act, a single institution or consortium of cooperating institutions which conducts clinical and other applied research, training programs, continuing education programs, and information programs with respect to methods of contraception, and infertility;

(n) For purposes of grants authorized by section 452C of the Act, an agency or institution which conducts research with respect to child health, and gives priority to the expeditious transfer of advances from basic science to clinical applications and improving the care of infants and children;

(o) For purposes of grants authorized by section 452E of the Act, a single institution or a consortium of cooperating institutions which conducts research for the purposes of improving the diagnosis and treatment of, and finding the cure for, fragile X;

(p) For purposes of grants authorized by section 464C of the Act, a single institution or a consortium of cooperating institutions which conducts basic and clinical research into, training in, information and continuing education programs for the health community and the general public about, and demonstration of, advanced diagnostic, prevention, and treatment methods for disorders of hearing and other communication processes and complications resulting from these disorders;

(q) For purposes of grants authorized by section 464N of the Act, institutions designated as National Drug Abuse Research Centers for interdisciplinary research relating to drug abuse and other biomedical, behavioral, and social issues related to drug abuse;

(r) For purposes of grants authorized by section 485F of the Act, a biomedical or behavioral research institution or consortia that:

(1) Have a significant number of members of minority health disparity populations or other health disparity populations enrolled as students in the institution (including individuals accepted for enrollment in the institution);

(2) Have been effective in assisting such students of the institution to complete the program of education or training and receive the degree involved;

(3) Have made significant efforts to recruit minority students to enroll in and graduate from the institution, which may include providing means-tested scholarships and other financial assistance as appropriate; and

(4) Have made significant recruitment efforts to increase the number of minority or other members of health disparity populations serving in faculty or administrative positions at the institution; or

(s) For the purposes of grants authorized in section 2316 of the Act, an entity for basic and clinical research into, and training in, advanced diagnostic, prevention, and treatment methods for acquired immunodeficiency syndrome (AIDS).

Director means the Director of NIH or the organizational component authorized to award grants to support centers under this part.

Grant(s) means, unless the context otherwise requires, an award of funds to support a center authorized under § 52a.1. The term includes cooperative agreement(s).

NIH means the National Institutes of Health and its organizational components that award grants.

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.

Project period means the period of time, from one to five years, specified in the notice of grant award that the NIH or the awarding component intends to support a proposed center without requiring the center to recompete for funds.

[57 FR 61006, Dec. 23, 1992, as amended at 61 FR 55108, Oct. 24, 1996; 68 FR 69621, Dec. 15, 2003]

§ 52a.3 Who is eligible to apply?

(a) Any public or private nonprofit agency, institution, or consortium of

agencies is eligible to apply for a grant under sections 409C, 414, 417, 417A, 422, 445, 445A, 445I, 447, 452A, and 2316 of the Act.

(b) Any public or private nonprofit or for-profit agency, institution, or consortium of agencies is eligible to apply for a grant under sections 428, 431, 434, 441, 452C, 452E, 464C, 464J, 464N, and 485F of the Act.

(c) Any applicant under this part must be located in a State, the District of Columbia, Puerto Rico, the Virgin Islands, the Canal Zone, Guam, American Samoa, or the successor States of the Trust Territory of the Pacific Islands (the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).

[57 FR 61006, Dec. 23, 1992, as amended at 61 FR 55109, Oct. 24, 1996; 68 FR 69622, Dec. 15, 2003]

§ 52a.4 What information must each application contain?

Each application under this part must include detailed information as to the following:

(a) The personnel, facilities, and other resources available to the applicant with which to initiate and maintain the proposed center grants program;

(b) Any research, training, demonstration, or information dissemination activities in which the applicant is currently engaged; the sources of funding for these activities; and the relevance of these activities to the proposed center grants program;

(c) Proposed research, training, demonstration, and information dissemination activities;

(d) The proposed organizational structure of the center and the relationship of the proposed center to the applicant organization(s);

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

(f) Proposed methods for monitoring and evaluating individual activities and the overall center program;

(g) Proposed methods for coordinating the center's activities, where appropriate, with similar efforts by other public and private organizations;

(h) The availability of any community resources necessary to carry out proposed activities; and

(i) Efforts to be made to generate and collect income from sources other than NIH to be used to further the purposes of the center program. NIH encourages these efforts. Income may include, but is not limited to, that generated from the sale or rental of products or services produced by grant-supported activities, such as laboratory tests, computer time, and payments received from patients or third parties, where appropriate (the disposition of grant-related income is governed by 2 CFR 200.307);

(j) The proposed budget for the center and a justification for the amount of the grant funds requested; and

(k) Any other information that the Director of the awarding institute may request.

(Approved under OMB Control Number 0925–0001)

[57 FR 61006, Dec. 23, 1992, as amended at 81 FR 3007, Jan. 20, 2016; 89 FR 80065, Oct. 2, 2024]

§ 52a.5 How will NIH evaluate applications?

(a) NIH considers the following in evaluating Center grant applications:

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

(2) The qualifications and experience of the center director and other key personnel;

(3) The statutory and program purposes to be accomplished;

(4) The extent to which the various components of the proposed program would be coordinated into one multidisciplinary effort within the center;

(5) The extent to which the center's activities would be coordinated with similar efforts by other organizations;

(6) The administrative and managerial capability of the applicant;

(7) The reasonableness of the proposed budget in relation to the proposed program; and

(8) Other factors which the awarding institute, center, or division considers appropriate in light of its particular statutory mission.

(b) Where required by statute or NIH policy, applications are reviewed by appropriate national advisory councils or

boards before awards are made. NIH grants may be awarded generally only after approval recommendations from both appropriate scientific peer review groups and national advisory councils or boards.

§ 52a.6 Information about grant awards.

(a) The notice of grant award specifies how long NIH 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.

(b) 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 the NIH that continued funding is in the best interest of the Federal Government.

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

(Approved under OMB Control Number 0925–0001)

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

A grantee shall spend funds it receives under this part solely in accordance with the approved application and budget, the authorizing legislation, 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.

[61 FR 55109, Oct. 24, 1996, as amended at 81 FR 3007, Jan. 20, 2016; 89 FR 80065, Oct. 2, 2024]

§ 52a.8 Other HHS regulations and policies that apply.

Several other regulations and policies apply to 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—Responsibilities 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 procedures

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 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

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 change, and interested persons should contact the Office of Research on Women's Health, NIH, Room 201, MSC 0161, BETHESDA, MD 20892–0601 (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 change, and interested persons should contact the Office of Recombinant DNA Activities, NIH, Suite 323, 6000 Executive Boulevard, MSA 7010, BETHESDA, MD 20892–7010 (301–496–9838; 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 of Laboratory Animal Welfare, Office of Extramural Research, NIH (Revised September 1986).

NOTE: This policy is subject to change, and interested persons should contact the Office of Laboratory Animal Welfare, Office of Extramural Research, NIH, Rockledge 1, 6705 Rockledge Drive, Bethesda, Maryland 20817, telephone 301–594–2382 (not a toll-free number) to obtain references to the current version and any amendments.

[57 FR 61006, Dec. 23, 1992, as amended at 61 FR 55109, Oct. 24, 1996; 68 FR 69622, Dec. 15, 2003; 81 FR 3007, Jan. 20, 2016; 89 FR 80065, Oct. 2, 2024]

§ 52a.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 the conditions are necessary to assure the carrying out of the purposes of the award, the interests of the public health, or the conservation of grant funds.

[61 FR 55110, Oct. 24, 1996]

PART 52b—NATIONAL INSTITUTES OF HEALTH CONSTRUCTION GRANTS

Sec.

AUTHORITY: 42 U.S.C. 216, 285a-2, 285a-3, 285b-3, 285b-4, 285d-6, 285i, 285m-3, 285o-4, 287a-2, 287a-3, 300cc-41.

SOURCE: 64 FR 63722, Nov. 22, 1999, unless otherwise noted.

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

(a) *General.* Except as provided in paragraph (c) of this section, this part applies to all grants awarded by NIH and its components for construction of new buildings and the alteration, renovation, remodeling, improvement, expansion, and repair of existing buildings, including the provision of equipment necessary to make the building (or applicable part of the building) suitable for the purpose for which it was constructed.

(b) *Specific programs covered.* From time to time the Director may publish a list of the construction 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 construction grant programs, including applications and instructions, may be obtained from the component of NIH that administers the program.

(c) *Specific programs excluded.* The regulations of this part do not apply to minor alterations, renovations, or repairs funded under a research project grant (see part 52 of this chapter) or alterations or renovations funded under an NIH center grant (see part 52a of this chapter).

§ 52b.2 Definitions.

As used in this part:

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

Construction means the construction of new buildings or the modernization of, or the completion of shell space in, existing buildings (including the installation of fixed equipment), but excluding the cost of land acquisition and off-site improvements.

Construction grant means funds awarded for construction in accordance with the applicable provisions of the Act and this part.