

Public Health Service, HHS

§ 63a.1

of the award or to carry out the purpose for which the award was made; or

(c) If the awardee is convicted of a felony, or an offense involving any illegal drug or substance, or any offense involving a lack of financial integrity or business honesty; or

(d) Because of programmatic changes or lack of funds.

[65 FR 66513, Nov. 6, 2000, as amended at 85 FR 72909, Nov. 16, 2020]

§ 63.10 Other HHS regulations and policies that apply.

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

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.

59 FR 14508 (March 28, 1994)—NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research. (NOTE: Interested persons should contact the Office of Research on Women's Health, NIH, Room 201, Building 1, MSC 0161, Bethesda, MD 20892-0161; telephone 301-402-1770 (not a toll-free number) to obtain copies of this policy.)

59 FR 34496 (July 5, 1994)—NIH Guidelines for Research Involving Recombinant DNA Molecules. (NOTE: Interested persons should contact the Office of Biotechnology Activities, NIH, Suite 323, 6000 Executive Boulevard, MSC 7010, Bethesda, MD 20892-7010; telephone 301-496-9838 (not a toll-free number) to obtain copies of the policy.)

“Public Health Service Policy on Humane Care and Use of Laboratory Animals” (Revised September 1986), Office of Laboratory Animal Welfare, NIH. (NOTE: Interested persons should contact the Office of Laboratory Animal Welfare, NIH, Rockledge

Building I, 6705 Rockledge Drive, Suite 1050, MSC 7982, Bethesda, MD 20892-7982; telephone 301-496-7163 (not a toll-free number) to obtain copies of the policy.)

[60 FR 10719, Feb. 27, 1995, as amended at 65 FR 66513, Nov. 6, 2000]

PART 63a—NATIONAL INSTITUTES OF HEALTH TRAINING GRANTS

Sec.

63a.1 To what programs do these regulations apply?

63a.2 Definitions.

63a.3 What is the purpose of training grants?

63a.4 Who is eligible for a training grant?

63a.5 How to apply for a training grant.

63a.6 How are training grant applications evaluated?

63a.7 Awards.

63a.8 How long does grant support last?

63a.9 What are the terms and conditions of awards?

63a.10 How may training grant funds be spent?

63a.11 Other HHS regulations and policies that apply.

AUTHORITY: 42 U.S.C. 216, 2421(b)(3), 284(b)(1)(C), 285g-10, 287c(b), 300cc-15(a)(1), 300cc-41(a)(3)(C), 7403(h)(2).

SOURCE: 61 FR 55111, Oct. 24, 1996, unless otherwise noted.

§ 63a.1 To what programs do these regulations apply?

(a) The regulations of this part apply to:

(1) Grants awarded by the John E. Fogarty International Center for Advanced Study in the Health Sciences, NIH, for training in international cooperative biomedical research endeavors, as authorized under section 307(b)(3) of the Act;

(2) Grants awarded by NIH for research training with respect to the human diseases, disorders, or other aspects of human health or biomedical research for which the institute or other awarding component was established, for which fellowship support is not provided under section 487 of the Act and which is not residency training of physicians or other health professionals, as authorized by sections 405(b)(1)(C), 452G, 485B(b), 2315(a)(1), and 2354(a)(3)(C) of the Act; and,

(3) Grants awarded by the National Institute of Environmental Health Sciences, NIH, for the education and

§ 63a.2

training of physicians in environmental health, as authorized under section 103(h)(2) of the Clean Air Act, as amended.

(b) The regulations of this part also apply to cooperative agreements awarded to support the training specified in paragraph (a) of this section. References to “grant(s)” shall include “cooperative agreement(s).”

(c) The regulations of this part do not apply to:

(1) Research training support under the National Research Service Awards Program (see part 66 of this chapter);

(2) Research training support under the NIH Center Grants programs (see part 52a of this chapter);

(3) Research training support under traineeship programs (see part 63 of this chapter);

(4) Research training support under the NIH AIDS Research Loan Repayment Program (see section 487A of the Act); or

(5) Research training support under the National Library of Medicine training grant programs (see part 64 of this chapter).

[61 FR 55111, Oct. 24, 1996, as amended at 71 FR 42296, July 26, 2006]

§ 63a.2 Definitions.

As used in this part:

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

HHS means the Department of Health and Human Services.

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

Nonprofit as applied to any agency or institution, means an agency or institution which is a corporation or association, no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

Program director means the single individual named by the grantee in the grant application and approved by the Secretary, who is responsible for the management and conduct of the training program.

Project period See § 63a.8(a).

Secretary means the Secretary of Health and Human Services and any other official of HHS to whom the authority involved is delegated.

42 CFR Ch. I (10–1–24 Edition)

Stipend means a payment to an individual to help meet that individual’s subsistence expenses during the training period.

Training grant means an award of funds to an eligible agency or institution for a training program authorized under § 63a.1 to carry out one or more of the purposes set forth in § 63a.3.

§ 63a.3 What is the purpose of training grants?

The purpose of a training grant is to provide financial assistance to an eligible agency or institution to enable it to provide research training to individuals in the diagnosis, prevention, treatment, or control of human diseases or disorders, or other aspects of human health or biomedical research, or in environmental health, in order to increase the number of facilities which provide qualified training and the number of persons having special competence in these fields.

§ 63a.4 Who is eligible for a training grant?

(a) *General.* Except as otherwise provided in this section or as prohibited by law, any public or private for-profit or nonprofit agency, institution, or entity is eligible for a training grant.

(b) *International training grants for AIDS research.* Any international organization concerned with public health is eligible for a training grant to support individuals for research training relating to acquired immunodeficiency syndrome (AIDS), as authorized under section 2315(a)(1) of the Act. In awarding these grants, preference shall be given to:

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

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

§ 63a.5 How to apply for a training grant.

Any agency, institution, or entity interested in applying for a grant under this part must submit an application at the time and in the form and manner that the Secretary may require.

§ 63a.6 How are training grant applications evaluated?

The Secretary shall evaluate applications through the officers and employees, experts, consultants, or groups engaged by the Secretary for that purpose, including review or consultation with the appropriate advisory council or other body as may be required by law. The Secretary's evaluation will be for merit and shall take into account, among other pertinent factors, the significance of the program, the qualifications and competency of the program director and proposed staff, the adequacy of the selection criteria for trainees under the program, the adequacy of the applicant's resources available for the program, and the amount of grant funds necessary for completion of its objectives.

§ 63a.7 Awards.

Criteria. Within the limits of available funds, the Secretary may award training grants for training programs which:

- (a) Are determined to be meritorious, and
- (b) Best carry out the purposes of the particular statutory program described in § 63a.1 and the regulations of this part.

§ 63a.8 How long does grant support last?

(a) The notice of the grant award specifies how long the Secretary intends to support the project without requiring the grantee to recompete for funds. This period, called the "project period," will usually be for one to five years.

(b) Generally, the grant will be initially for one year and subsequent continuation awards will be for one year at a time. A grantee must submit a separate application at the time and in the form and manner that the Secretary may require to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of these 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 determination by the Secretary that con-

tinued 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.

(d) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward to the next budget period, for use as prescribed by the Secretary, provided that a continuation award is made. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for that period, the Secretary may adjust the amounts awarded by withdrawing the excess.

§ 63a.9 What are the terms and conditions of awards?

In addition to the requirements imposed by law, grants awarded under this part are subject to any terms and conditions imposed by the Secretary to carry out the purpose of the grant or assure or protect advancement of the approved program, the interests of the public health, or the conservation of grant funds.

§ 63a.10 How may training grant funds be spent?

(a) *Authorized expenditures; general.* A grantee shall expend funds it receives under this part solely in accordance with the approved application and budget, the regulations of this part, the terms and conditions of the grant award, and the applicable cost principles in 45 CFR part 75, subpart E.

(b) *Authorized categories of expenditures.* Subject to any limitations imposed in the approved application and budget or as a condition of the award, grant funds may be expended for the following costs:

- (1) Expenses of the grantee in providing training and instruction under

§ 63a.11

42 CFR Ch. I (10–1–24 Edition)

the particular program, including salaries of faculty and support personnel, and the costs of equipment and supplies;

(2) Stipends and allowances to individuals during the period of their training and instruction; and,

(3) If separately justified and authorized under the particular program, tuition, fees, and trainee travel expenses which are necessary to carry out the purpose of the training grant.

(c) *Expenditures not authorized.* Grant funds may not be expended for:

(1) Compensation for employment or for the performance of personal services by individuals receiving training and instruction; or

(2) Payments to any individual who does not meet the minimum qualifications for training and instruction established by the grantee and approved by the Secretary or who has failed to demonstrate satisfactory participation in the training in accordance with the usual standards and procedures of the grantee.

[61 FR 55111, Oct. 24, 1996, as amended at 81 FR 3009, Jan. 20, 2016]

§ 63a.11 Other HHS regulations and policies that apply.

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

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 75—Uniform administrative requirements, cost principles, and audit requirements for HHS Awards

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 change, 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 change, 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.

“NIH Grants Policy Statement,” (December 1, 2003). This version is located on the NIH Web site at: <http://grants.policy.nih.gov/index.htm>.

NOTE: This policy is subject to change, and interested persons should contact the Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research, NIH, 6701 Rockledge Drive, Suite 350, MSC 7974, Bethesda, Maryland 20892-7974, telephone 301-435-0938 (or toll-free 800-518-4726), to obtain references to the current version and any amendments. Information may also be obtained by contacting the OPERA Division of Grants Policy via e-mail at [http://GrantsPolicy@mail.nih.gov](mailto:GrantsPolicy@mail.nih.gov). Previous versions of the NIH Grants Policy Statement are archived at <http://grants.nih.gov/grantspolicy/policy.htm>.

“Public Health Service Policy on Humane Care and Use of Laboratory Animals,” Office of Laboratory Animal Welfare (Amended August, 2002).

NOTE: This policy is subject to change, and interested persons should contact the Office of Laboratory Animal Welfare, 6705 Rockledge Drive, Suite 360, MSC 7982, Bethesda, Maryland 20892-7982, telephone 301-594-2382 (not a toll-free number), to obtain references to the current version and any amendments. Information may also be obtained by browsing the Office of Laboratory

Animal Welfare Home Page site on the World Wide Web (<http://www.grants.nih.gov/grants/olaw/olaw.htm>).

[61 FR 55111, Oct. 24, 1996, as amended at 71 FR 42296, July 26, 2006; 81 FR 3009, Jan. 20, 2016]

PART 64—NATIONAL LIBRARY OF MEDICINE TRAINING GRANTS

Sec.

- 64.1 Programs to which these regulations apply.
- 64.2 Definitions.
- 64.3 Who is eligible for a grant?
- 64.4 How to apply for a grant.
- 64.5 How are grant applications evaluated?
- 64.6 Awards.
- 64.7 What other conditions apply?
- 64.8 How may funds be used?
- 64.9 Other HHS regulations that apply.

AUTHORITY: 42 U.S.C. 216, 286b-3.

SOURCE: 56 FR 29192, June 26, 1991, unless otherwise noted.

§ 64.1 Programs to which these regulations apply.

(a) The regulations of this part apply to grants under section 472 of the Public Health Service Act (42 U.S.C. 286b-3) to public and private nonprofit institutions to assist in developing, expanding, and improving training programs (excluding training in a biomedical specialty and residency training) in library science and the field of communications of information pertaining to sciences relating to health.

(b) The regulations of this part also apply to cooperative agreements awarded for these purposes. References to "grant(s)" shall include "cooperative agreement(s)."

(c) The regulations of this part do not apply to research training support under the National Research Service Awards Program (see part 66 of this chapter).

§ 64.2 Definitions.

As used in this part:

HHS means the Department of Health and Human Services.

Nonprofit private entity means an agency, organization, institution, or other entity which may not lawfully hold or use any part of its net earnings to the benefit of any private shareholder or individual which does not

hold or use its net earnings for that purpose.

Other trainee costs means those costs other than stipends, such as tuition, fees, and trainee travel, which are directly associated with and necessary for the training of individuals receiving stipends and which are incurred within the period of training.

Project director means the single individual named by the grantee in the grant application and approved by the Secretary, who is responsible for the management and conduct of the project.

Project period. See § 64.6(b).

Secretary means the Secretary of Health and Human Services and any other official of HHS to whom the authority involved is delegated.

Stipend means a payment to an individual that is intended to help meet that individual's subsistence expenses during training.

Training grant means an award of funds to an eligible entity for a project authorized under § 64.1(a).

§ 64.3 Who is eligible for a grant?

Except as otherwise prohibited by law, any public or private nonprofit entity is eligible for a training grant.

§ 64.4 How to apply for a grant.

Applications for grants must include the following information:

(a) *Required information on the proposed project.* (1) The nature, duration, and purpose of the training for which the application is filed.

(2) The name and qualifications of the project director and any key personnel responsible for the proposed project.

(3) A description of the facilities, staff, support services, and other organizational resources available to carry out the project.

(4) The intended number of trainees and the minimum qualifications and criteria for their selection.

(5) A description of the plan for evaluating the proposed project.

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

(b) *Required information on costs.* (1) A budget for the proposed project and a