

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 63a

RIN 0905-AD56

National Institutes of Health Training Grants

AGENCY: National Institutes of Health, Public Health Service, Department of Health and Human Services.

ACTION: Notice of proposed rulemaking.

SUMMARY: The National Institutes of Health (NIH) proposes to issue regulations governing non-National Research Service Award (NRSA) training grants awarded under Public Health Service (PHS) Act, and the Clean Air Act, as amended. Regulations which at one time governed both NIH training grants and training grants specific to the National Library of Medicine (NLM) were revised in June of 1991 as part of the overall updating of all regulations concerning NLM, and now govern only NLM-specific training grants. New regulations are required to implement other non-NRSA research training grant authorities set forth in the National Institutes of Health Revitalization Act of 1993, the Clean Air Act, and other health research-related legislation.

DATES: Comments must be received on or before March 27, 1995. Any regulations which are adopted will be effective 30 days after publication in the **Federal Register**.

ADDRESSES: Comments should be sent to Mr. Jerry Moore, Regulatory Affairs Officer, National Institutes of Health, Building 31, Room 1B-25, 31 Center DR MSC 2075, 9000 Rockville Pike, Bethesda, Maryland 20892-2340.

FOR FURTHER INFORMATION CONTACT: Mr. Jerry Moore at the address above, or telephone (301) 496-4606 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The principal financial assistance support mechanism for research training by NIH and its constituent award-making organizations is through the NRSA program, authorized by section 487 of the PHS Act and addressed in regulations found at 42 CFR part 66. The regulations which NIH proposes to issue concerning training grants would not affect the NRSA Program or amend the regulations in part 66.

Prior to the advent of the NRSA program, the NIH institutes had used training authority contained in section 301 of the PHS Act and related sections that authorized each institute to conduct

or support research training. The NRSA program generally replaced this training authority, except in a few isolated cases.

In 1985, the Congress, in a major revision of NIH's authorities, the Health Research Extension Act of 1985 (Public Law 99-158), authorized the directors of the research institutes of NIH to conduct (at NIH) and support non-NRSA research training. This authority, as set forth in section 405(b)(1)(C) of the PHS Act, is limited to research training for which fellowship support is not provided under the NRSA program and which is not residency training of physicians or other health professionals.

Subsequently, on June 26, 1991, NIH published a final rule in the **Federal Register** (56 FR 29187 et seq.) revising regulations at 42 CFR part 64, (then) entitled National Institutes of Health and National Library of Medicine Training Grants, as part of the overall updating of all regulations concerning the National Library of Medicine. As a result, part 64 now addresses only NLM training grants authorized by section 472 of the PHS Act. NIH needs to provide regulations for research training grant authorities not otherwise addressed in the NLM-specific regulations in part 64.

NIH also needs to provide regulations for training grants authorized by section 901 of the Clean Air Act Amendments of 1990, Public Law 101-549, which amended section 103(h)(2) of the Clean Air Act. Section 901 directs the Director of the National Institute of Environmental Health Sciences (NIEHS) to conduct a program for the education and training of physicians in environmental health.

In 1993, the Congress, in the most recent major revision of NIH's authorities, the NIH Revitalization Act of 1993 (Public Law 103-43), authorized the Director of the National Center for Human Genome Research (NCHGR), as set forth in PHS Act section 485B(b), to conduct and support training in human genome research for which fellowship support is not provided under PHS Act section 487 and that is not residency training of physicians or other health professionals. In codifying the establishment of the Office of AIDS Research (OAR), Public Law 103-43 also authorized the Director of OAR, in carrying out AIDS research, to support the training of American scientists abroad and foreign scientists in the United States, as set forth in section 2354(a)(3)(C) of the PHS Act.

Additionally, section 2315(a)(1) of the PHS Act directs the Secretary, acting through the Director of NIH, to make grants to international organizations concerned with public health to

promote and expedite international research and training concerning the natural history and pathogenesis of the human immunodeficiency virus and the development and evaluation of vaccines and treatments for acquired immunodeficiency syndrome (AIDS) and opportunistic infections. The John E. Fogarty International Center for Advanced Study in the Health Sciences (FIC), NIH, also awards grants for training in international cooperative biomedical research endeavors to public and nonprofit private institutions in the United States and participating foreign countries under section 307(b)(3) of the PHS Act.

NIH proposes to issue new regulations at part 63a to govern implementation of these training grant authorities. The regulations are intended to serve as a permanent set of regulations that can be adapted for future training grant programs (both research training and non-research training). Since the rules for training programs are largely the same irrespective of the funding source, it makes sense to have a single set of uniform rules that applies to all NIH training grant programs, with any exceptions or special provisions for particular programs as necessary.

Readers of this notice should understand that in publishing the new regulations, NIH is not initiating any new training programs. Rather, NIH is simply establishing regulations to govern existing training grant authorities.

This Notice of Proposed Rulemaking (NPRM) sets forth what training is covered by the regulations, the nature and purpose of the training, what institutions are eligible to apply, how to apply, how grants are awarded, and conditions imposed on recipients. The purpose of this NPRM is to invite public comment on the proposed regulations. Implementation of the particular training grant programs encompassed by these proposed regulations rests with the statutorily authorized awarding organizations and is subject to the availability of funding for the purpose, as well as programmatic priorities determined by the awarding organizations.

Public Law 103-227, enacted on March 31, 1994, prohibits smoking in certain facilities in which minors will be present. The Department of Health and Human Services is now preparing to implement the provisions of that law. Until those implementation plans are in place, PHS continues to strongly encourage all grant recipients to provide a smoke-free workplace and promote the nonuse of all tobacco products.

The following statements are provided for the information of the public.

Regulatory Impact Statement

Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, requires the Department to prepare an analysis for any rule that meets one of the E. O. 12866 criteria for a significant regulatory action; that is, that may—

Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866.

In addition, the Department prepares a regulatory flexibility analysis, in accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. chapter 6), if the rule is expected to have a significant impact on a substantial number of small entities.

For the reasons outlined below, we do not believe this NPRM is economically significant nor do we believe that it will have a significant impact on a substantial number of small entities. In addition, this NPRM is not inconsistent with the actions of any other agency.

This NPRM merely codifies internal policies and procedures of the Federal government used to administer non-NRSA training grants awarded by the directors of the national research institutes of NIH under the authority set forth in section 405(b)(1)(C) of the PHS Act; the Director, FIC, under the authority in section 307 of the PHS Act delegated by the Secretary; the Director, NCHGR, under the authority set forth in section 485B(b) of the PHS Act; the Secretary, acting through the Director of NIH, under the authority set forth in section 2315(a)(1) of the PHS Act; the Director of the Office of AIDS Research under the authority set forth in section 2354(a)(3)(C) of the PHS Act; and the Director of NIEHS under the authority set forth in section 103(h)(2) of the Clean Air Act. These grants do not have a significant economic or policy impact on a broad cross-section of the public. Furthermore, the proposed regulations would only affect those highly qualified

health professionals and institutions interested in participating in non-NRSA research training programs, subject to the normal accountability requirements for program participation. No individual or institution is obligated to participate in the program.

For these same reasons, the Secretary certifies that this NPRM will not have a significant economic impact on a substantial number of small entities, and that a Regulatory Flexibility Analysis, as defined under the Regulatory Flexibility Act of 1980, is not required.

Paperwork Reduction Act

This NPRM does not contain any information collection requirements which are subject to Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35).

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance (CFDA) numbered program affected by these proposed regulations is:

93.837—Heart and Vascular Diseases Research

List of Subjects in 42 CFR Part 63a

Environmental health; Grant programs—health; Health; Medical research.

Dated: November 7, 1994.

Philip R. Lee,

Assistant Secretary for Health.

Approved: December 27, 1994.

Donna E. Shalala,

Secretary.

Accordingly, it is proposed to amend chapter 1 of title 42 of the Code of Federal Regulations by adding a new part 63a to read as set forth below.

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, 242(b)(3), 284(b)(1)(C), 287c(b), 300cc-15(a)(1), 300cc-41(a)(3)(C), 7403(h)(2).

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

(b) These regulations 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 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 National Library of Medicine training grant programs (see part 64 of this chapter).

§ 63a.2 Definitions.

As used in this part: "Act" means the Public Health Service Act, as amended (42 U.S.C. 201 et seq.).

"Cooperative agreement" See § 63a.1(b).

"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.

"Stipend" means a payment to an individual that is intended 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 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 for projects to support individuals for research training relating to acquired immunodeficiency syndrome (AIDS) authorized under section 2315(b)(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, projects 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 (program) without requiring the grantee to re compete 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 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.

(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 any 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 section 74.27.

(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 costs within the following expense categories:

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

§ 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 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
51 FR 16958 (May 7, 1986)—NIH Guidelines for Research Involving Recombinant DNA Molecules
59 FR 14508 (as republished March 28, 1994)—NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research
Public Health Service Grants Policy Statement, DHHS Publication No. (OASH)94-50,000 (Rev.) April 1, 1994.
Public Health Service Policy on Humane Care and Use of Laboratory Animals, Office for Protection from Research Risks, NIH (Revised September 1986).

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