

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Public Health Service****42 CFR Part 63**

RIN 0905-AD28

Traineeships

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Final rule.

SUMMARY: This final rule revises regulations governing National Institutes of Health (NIH) research traineeship awards in their entirety. The regulations are obsolete and require revision. The revised regulations are intended to provide NIH with the flexibility needed to effectively support the development and operation of a variety of training programs essential to the NIH research mission.

EFFECTIVE DATE: This final rule is effective March 29, 1995.

FOR FURTHER INFORMATION CONTACT: Mr. Jerry Moore, Regulatory Affairs Officer, National Institutes of Health, Building 31, Room 1B25, 31 Center DR MSC, 9000 Rockville Pike, Bethesda, Maryland 20892-2075, telephone (301) 496-4606 (not a toll-free number). For information concerning the program contact the Office of Education, National Institutes of Health, Building 10, Room 1C129, 9000 Rockville Pike, Bethesda, Maryland 20892-0001, telephone (301) 496-2427 (not a toll-free number).

SUPPLEMENTAL INFORMATION: On August 6, 1993 (58 FR 42039), NIH published a notice of proposed rulemaking in the Federal Register announcing its intention to revise in their entirety the regulations at 42 CFR part 63 governing traineeships to cover traineeships awarded under sections 404E(d)(2), 405(b)(1)(C), 472, and 484 of the Public Health Service (PHS) Act, as amended.

Traineeships under part 63 are designed to provide research training for which fellowship support is not provided under section 487 of the PHS Act, and which is not residency training of physicians or other health professionals. The traineeships provide opportunities for developmental training and practical research experience in the labs of NIH, and are available to postdoctoral scientists at the beginning stages of their professional research careers, and to high school, college, graduate and professional (e.g. medical, dental, and other health fields) school students pursuing studies in academic disciplines related to

biomedical research and in medical library science and related fields.

NIH received no comments concerning the NPRM. However, enactment of the NIH Revitalization Act of 1993, Public Law 103-43, necessitated making several technical changes to the proposed regulations to conform to the regulations to Public Law 103-43. More specifically, Public Law 103-43 redesignated the National Center for Nursing Research as the National Institute of Nursing Research.

Accordingly, references to the National Center for Nursing Research in paragraph (a) of § 63.1 and in the definition for the term "Director" in § 63.2 were deleted. This redesignation also eliminated the need for the reference to PHS Act section 484.

Accordingly, references to section 484 were deleted from the authority citation, paragraph (a) of § 63.1, and the definitions for the terms "Award," "Awardee" and "Traineeship" in § 63.2.

Public Law 103-43 also set forth new traineeship authority for the Director of the National Center for Human Genome Research (NCHGR) in PHS Act section 485B and the Director of the Office of Alternative Medicine (OAM) in PHS Act section 404E(d)(2). Accordingly, references to the NCHGR and OAM authorities were added to paragraph (a) of § 63.1 and to the definition for the term "Director" in § 63.2. In addition, references to PHS Act section 485B and 404E were added to the authority citation, paragraph (a) of § 63.1, and to the definitions for the terms "Award," "Awardee," and "Traineeship" in § 63.2.

Additionally, Public Law 103-43 required NIH to establish guidelines on the inclusion of women and minorities and their subpopulations in research involving human subjects, including clinical trials, supported by NIH. These guidelines, which were originally published in the Federal Register on March 9, 1994 (59 FR 1146), were republished on March 28, 1994 (59 FR 14508) because of typesetting problems. Section 63.10 of the regulations was modified to include a reference for these guidelines.

In accordance with section 553 of title 5 of the United States Code, NIH finds that good cause exists for waiving another NPRM. Delay of this rule would be contrary to the public interest and unnecessary given the technical nature of these changes.

Further, PHS strongly encourages all grant recipients to provide a smoke-free workplace and to promote the nonuse of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities

that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

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, the Secretary does not believe this rule is economically significant nor does the Secretary believe that it will have a significant impact on a substantial number of small entities. In addition, this proposed rule is not inconsistent with the actions of any other agency.

This proposed rule merely codifies internal policies and procedures of the Federal government currently used to administer traineeship awards. The program does not have a significant economic or policy impact on a broad cross-section of the public. Furthermore, this rule will only affect those few highly qualified health professionals who are interested in participating in the program, subject to the normal accountability requirements for program participation. No individual is obligated to participate in the program. For these same reasons, the Secretary certifies this proposed rule 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 rule contains information collection requirements subject to Office of Management and Budget (OMB) review and approval under the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35).

Title: National Institutes of Health Research Traineeships.

Description: The information collected is used by NIH to determine an applicant's eligibility to apply for a traineeship, ensures that an awardee agrees to comply with the terms and conditions of the traineeship and that an awardee shows good cause for not

reimbursing PHS for any overpayment of stipends or other allowances because of early termination of the traineeship or for any other reason.

Respondent Description: Individuals or households.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

	Annual number of respondents	Annual frequency	Average burden per response	Annual burden hours
Reporting: § 63.6(b)				
Summer Fellowship Applicants	3,000	1	1	3,000
Predocctoral & Postdoctoral Applicants	400	1	1	400
Summer Fellowship References	6,000	1	.33	2,000
Predocctoral & Postdoctoral References	1,200	1	.33	400
Subtotal	10,600	1	.55	15,800
§ 63.8(c)	100	1	.25	25
§ 63.9(a)	100	1	.25	25
Total				50

¹ This burden is approved under OMB Approval Number 0925-0299 (expires April 30, 1997).

The information collection in § 63.6(b) regarding application materials and the associated burden are approved under OMB Approval Number 0925-0299 (expires April 30, 1997). The information collection in § 63.8(c) and § 63.9(a), and the associated burden have been reported to OMB for review and approval under OMB Approval Number 0925-0299.

Catalog of Federal Domestic Assistance
 Catalog of Federal Domestic Assistance program numbers affected by this rule are: 93.140 and 93.172.

List of Subjects in Part 63

Grant programs—health; Health; Medical research.

Dated: December 16, 1994.

Philip R. Lee,

Assistant Secretary for Health.

Approved: February 16, 1995.

Donna E. Shalala,
 Secretary.

Accordingly, part 63 of title 42 of the Code of Federal Regulations is revised to read as set forth below.

PART 63—TRAINEESHIPS

Sec.

- 63.1 To what programs do these regulations apply?
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63.9 How may NIH terminate awards?
 63.10 Other HHS regulations and policies that apply.

Authority: 42 U.S.C. 216, 283g(d), 284(b)(1)(C), 286b-3, 287c(b).

§ 63.1 To what programs do these regulations apply?

(a) The regulations in this part apply to research traineeships awarded by each Director of a national research institute of NIH, the Director of the National Library of Medicine (NLM), the Director of the National Center for Human Genome Research (NCHGR), the Director of the Office of Alternative Medicine, or designees pursuant to sections 404E(d)(2), 405(b)(1)(C), 472, and 485B of the Public Health Service Act, as amended.

(b) The regulations of this part do not apply to research training which is part of the National Research Service Award Program provided under 42 CFR part 66, the Mental Health Traineeship Program provided under 42 CFR part 64a, or residency training of physicians or other health professionals.

§ 63.2 Definitions.

As used in this part:

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

“Award” means an award of funds under sections 404E(d)(2), 405(b)(1)(C), 472, or 485B of the Act, or other sections of the Act which authorize research training or traineeships.

“Awardee” means an individual awarded a traineeship under sections 404E(d)(2), 405(b)(1)(C), 472, or 485B of

the Act, or other sections of the Act which authorize research training or traineeships.

“Director” means the director of one of the national research institutes of NIH specified in section 401(b)(1) of the Act, the Director of the National Library of Medicine, the Director of the National Center for Human Genome Research, the Director of the Office of Alternative Medicine, or any official of NIH to whom the authority involved has been delegated.

“HHS” means the Department of Health and Human Services.

“NIH” means the National Institutes of Health.

“PHS” means the Public Health Service.

“Traineeship” means an award of funds under section 404E(d)(2), 405(b)(1)(C), 472, or 485B of the Act, or other sections of the Act authorizing research training or traineeships, and the regulations of this part, to a qualified individual for the person's subsistence and other expenses during a period in which the awardee is acquiring the research training approved under the award.

§ 63.3 What is the purpose of traineeships?

The purpose of an NIH research traineeship is to provide support for financial subsistence to an individual during a period in which the awardee is acquiring training in:

- (a) Basic and/or clinical biomedical or behavioral research relating to human health, including extending healthy life and reducing the burdens of illness, or

(b) Medical library science or related fields pertaining to sciences related to health or the communication of health sciences information.

Traineeships are intended to make available in the United States an increased number of persons having special competence in these research fields through developmental training and practical research experience in the facilities of NIH, with supplemental training at other qualified institutions (see § 63.8(a)).

§ 63.4 What are the minimum qualifications for awards?

Minimum qualifications for any traineeship shall be established by the Director and shall be uniformly applicable to all applicants in each traineeship program. These minimum qualifications may include requirements as to citizenship, medical standards, academic degrees, professional or other training or experience, and other factors as may be necessary to the fulfillment of the purpose of the traineeship. The Director may, as a matter of general policy or, in individual cases, waive compliance with any minimum qualification so established to the extent that the applicant or applicants have substantially equivalent qualifications or have such special training, experience or opportunity for service as to make an award particularly appropriate, and to the extent the Director finds it is consistent with the fulfillment of the purpose of the traineeship.

§ 63.5 How will NIH make awards?

Subject to the regulations of this part, the Director may award traineeships to those qualified applicants who are best able in that official's judgment to carry out the purpose of the traineeships. These awards may be made for a period of one (1) year or other period, including extensions or renewals, as may be specified.

§ 63.6 How to apply.

(a) Application for a traineeship shall be made in writing as prescribed by the Director.

(b) In addition to other pertinent information, the Director may require each applicant to submit the following information:

- (1) Certification of the applicant's citizenship status;
- (2) The applicant's educational background and other qualifications and experience, including previous academic and professional degrees, if any; and
- (3) The subject area of the proposed training.

(c) By applying, eligible individuals agree to abide by HHS, PHS, and NIH regulations, and the terms and conditions of the traineeship award which may require compliance with policies and procedures that apply to the proper conduct of research, such as research involving human and animal subjects, patient care, hospital and laboratory procedures, handling of confidential information, and outside employment.

§ 63.7 What are the benefits of awards?

(a) Subject to the availability of funds, each individual awarded a traineeship may receive a stipend fixed in an amount determined by the Director.

(b) Additional allowances and benefits may be authorized by and at the discretion of the Director, taking into account the cost of living and other factors such as the requirements of the training program and availability of discretionary funds. Discretionary allowances and benefits may include: health benefits coverage; dependents' allowance; travel to pre-award interviews, to first duty station, and return to the place of origin upon conclusion of the traineeship; tuition and institution fees; and other specific costs as may be necessary to fulfill the purpose of the training program.

§ 63.8 What are the terms and conditions of awards?

All traineeships shall be subject to the following terms and conditions:

(a) Training must be carried out at a facility of the NIH, but may be supplemented by additional training acquired at another institution which is found by the Director to be directly related to the purpose of the traineeship and necessary to its successful completion.

(b) Payments shall be made to the awardee or to the institution for payment to the awardee in accordance with payment schedules as prescribed by the Director for each traineeship program.

(c) The awardee shall reimburse NIH for any overpayment of stipends or other allowances because of early termination of the traineeship or any other reason, unless waived for good cause shown by the awardee.

(d) The Director may establish procedures and requirements applicable to traineeship awards, consistent with the regulations in this part, regarding:

- (1) The proper conduct of research investigations, including research involving human and animal subjects;
- (2) patient care;
- (3) hospital and laboratory procedures;
- (4) handling of confidential information;
- (5) outside

employment; and (6) additional conditions the Director finds necessary to fulfill the purpose of the traineeship.

(e) The awardee shall sign an agreement to comply with the terms and conditions of the traineeship.

§ 63.9 How may NIH terminate awards?

The Director may terminate a traineeship at any time:

(a) Upon written request of the awardee; or

(b) If it is determined that the awardee is ineligible, has materially failed to comply with the terms and conditions of the award, or to carry out the purpose for which it was made.

§ 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
- 51 FR 16958 (May 7, 1986)—NIH Guidelines for Research Involving Recombinant DNA Molecules
- “Public Health Service Policy on Humane Care and Use of Laboratory Animals,” Office for Protection from Research Risks, NIH (Revised September 1986)
- 59 FR 14508 (March 28, 1994)—NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research

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