## 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 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 trails, 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.