## 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.

Šubsequently, 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.