

with one or more specified aspects of the project.

* * * * *

7. Section 52.8 is revised to read as follows:

§ 52.8 Other HHS policies and regulations that apply.

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

- 37 CFR part 401—Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements
- 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
- 42 CFR part 50, subpart F—Responsibility of applicants for promoting objectively in research for which PHS funding is sought
- 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
- 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 changes, 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 changes, 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.]

“PHS Grants Policy Statement,” DHHS Publication No. (OASH) 94-50,000 (Rev.) April 1, 1994.

[Note: This policy is subject to changes, and interested persons should contact the Grants Policy Branch, OASH, Room 17A45, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857 (301-443-1874; not a toll-free number) to obtain references to the current version and any amendments.]

“Public Health Service Policy on Humane Care and Use of Laboratory Animals,” Office for Protection from Research Risks, NIH (Revised September 1986).

[Note: This policy is subject to changes, and interested persons should contact the Office for Protection from Research Risks, NIH, Suite 3B01, 6100 Executive Boulevard, MSC 7507, Rockville, MD 20852-7507 (301-496-7005; not a toll-free number) to obtain references to the current version and any amendments.]

8. The heading of § 52.9 is revised to read as follows:

§ 52.9 Additional conditions.

[FR Doc. 96-26976 Filed 10-23-96; 8:45 am]

BILLING CODE 4140-01-M

42 CFR Parts 52a and 54a

RIN 0905-AE00

National Institutes of Health Center Grants

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

ACTION: Final rule.

SUMMARY: The National Institutes of Health (NIH) is amending its center grants regulations in order to incorporate changes necessitated by enactment of the ADAMHA Reorganization Act and the National

Institutes of Health Revitalization Act of 1993, and is merging the regulations governing its grants for national alcohol research centers with its center grant regulations in accordance with the goals of the President's Regulatory Reinvention Initiative.

EFFECTIVE DATE: This final rule is effective on November 25, 1996.

FOR FURTHER INFORMATION CONTACT:

Mr. Jerry Moore, NIH Regulatory Affairs Officer, National Institutes of Health, Building 31, Room 1B25, 31 Center Dr., MSC 2075, Bethesda, MD 20892-2075, telephone (301) 496-4606 (not a toll-free number). For program information contact the Office of Extramural Research, National Institutes of Health, Shannon Building, Room 144, One Center Dr., MSC 0152, Bethesda, MD 20892-0152, telephone (301) 496-1096 (not a toll-free number).

SUPPLEMENTARY INFORMATION: On July 10, 1992, the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Reorganization Act, Public Law 102-321, was enacted. That Act restructured the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) by transferring the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), and the National Institute of Mental Health (NIMH) to NIH, effective October 1, 1992, and provided for the administration of treatment and service programs under a newly created Substance Abuse and Mental Health Services Administration (SAMHSA). Section 122 of that Act transferred Public Health Service (PHS) Act section 511, “National Alcohol Research Center,” to title IV, part C, subpart 14 of the Act, and redesignated the section as PHS Act section 464J. Under section 464J, the Secretary, acting through NIAAA, may designate National Alcohol Research Centers for the purpose of interdisciplinary research relating to alcoholism and other biomedical, behavioral and social issues related to alcoholism and alcohol abuse, and shall make annual grants to the Centers, including a grant to a designated Center for research on the effects of alcohol on the elderly.

Additionally, section 123 of the ADAMHA Reorganization Act added a new section 464N to the PHS Act which authorizes the Director of NIDA to designate National Drug Abuse Research Centers for the purpose of interdisciplinary research relating to drug abuse and other biomedical, behavioral, and social issues related to drug abuse. Under section 464N, the

Director of NIDA is authorized to make annual grants to these Centers.

Subsequently, the National Institutes of Health Revitalization Act of 1993, Public Law 103-43, was enacted on June 10, 1993. Provisions of that Act authorized several new center grant programs that should be covered by part 52a. Specifically, section 417 of the PHS Act, as added by section 401 of Public Law 103-43, authorizes centers for breast cancer research; section 417A of the PHS Act, as added by section 402 of Public Law 103-43, authorizes prostate cancer research and demonstration centers; section 422 of the PHS Act, as amended by section 502 of Public Law 103-43, authorizes centers for the study of pediatric cardiovascular diseases; section 431 of the PHS Act, as amended by section 601 of Public Law 103-43, authorizes centers for research and training regarding nutritional disorders, including obesity; section 447 of the PHS Act, as added by section 902 of Public Law 103-43, authorizes research centers regarding chronic fatigue syndrome; section 452A of the PHS Act, as added by section 1001 of the Public Law 103-43, authorizes research centers with respect to contraception and infertility; and section 452C of the PHS Act, as added by section 1021 of Public Law 103-43, authorizes child health research centers.

NIH published proposed amendments to its center grant regulations codified at 42 CFR part 52a, in a notice of proposed rule making (NPRM) published in the Federal Register February 17, 1995 (60 FR 9560). NIH also published another NPRM in the Federal Register August 19, 1994 (59 FR 42793), in which it published proposed amendments to the regulations codified at 42 CFR part 54a governing grants for national alcohol research centers in order to set forth changes necessitated by enactment of the ADAMHA Reorganization Act.

Subsequently, in March 1995, the President announced the Administration's plan for reform of the Federal regulatory system. In accordance with the goals of the President's Regulatory Reform Initiative, part of the President's Reinventing Government effort, NIH decided to merge the regulations governing grants for national alcohol research centers with the center grants regulations, thereby creating a single uniform set of rules governing all of its center grant programs set forth in title IV of the PHS Act.

Accordingly, the authority citation of part 52a is revised to include the U. S. Code citations for the new center grant authorities set forth in PHS Act sections 417, 417A, 422, 431, 447, 452A, 452C,

and 464N, and for the authority pertaining to grants for national alcohol research centers set forth in PHS Act section 464J. Part 54a, entitled, "Grants For Alcohol Abuse And Alcoholism Prevention, Treatment, And Rehabilitation Services And National Alcohol Research Centers," is removed from the Code of Federal Regulations.

Section 52a.1 is amended by adding language reflecting the applicability of part 52a to these new center grant programs and the grants for national alcohol research centers program, and is restructured for improved clarity into three separate paragraphs. Language is added in the first paragraph to clarify that center grants awarded under sections 441, 464C, and 2316 of the PHS Act include payments for alteration, remodeling, improvement, expansion, and repair of existing buildings, and the provision of equipment necessary to make them suitable for use as a center.

Section 52a.2 is amended by adding definitions of the terms "Director", "Grant(s)", and "Project period", and revising the definition of the term "Center" to include each new type of center and the national alcohol research centers.

Section 52a.3 is amended by adding references to PHS Act sections 417, 417A, 431, 447, 452A, 452C, and 464J in paragraph (a) and adding a reference to PHS Act section 464N in paragraph (b).

Section 52a.7 is amended to correct the reference to 45 CFR part 74.

In section 52a.8, the references to 45 CFR part 74, the guidelines for research involving recombinant DNA and the PHS policy on the care and use of laboratory animals are amended to reflect Federal Register format requirements, and references to the regulations to ensure objectivity in PHS-funded research at 42 CFR part 50, subpart F, and the NIH Guidelines on the Inclusion of Women and Minorities as Human Subjects in Clinical Research are added. The title of § 52a.8 is amended to reflect that policies, as well as regulations, are referenced.

Finally, the Department 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.

Pursuant to section 553 of the Administrative Procedure Act (5 U.S.C. 553), we have concluded that the publication of another NPRM is unnecessary because the changes to

merge the national alcohol research centers regulations with the center grants regulations are technical in nature and do not require any substantive changes in the center grants regulations or the national alcohol research centers regulations, as they were proposed. Only one comment was received concerning the previously published NPRMs. That comment indicated support for the proposed changes to the center grant regulations. No comments were received concerning the proposed changes to the national alcohol research centers regulations.

The following statements are provided as information for the public.

Executive Order 12866

Executive Order 12866 requires that all regulatory actions reflect consideration of the costs and benefits they generate, and that they meet certain standards, such as avoiding the imposition of unnecessary burdens on the affected public. If a regulatory action is deemed to fall within the scope of the definition of the term "significant regulatory action" contained in section 3(f) of the Order, pre-publication review by the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA) is necessary. This rule was reviewed under Executive Order 12866 and was determined to be not significant.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. chapter 6) requires that regulatory actions be analyzed to determine whether they create a significant impact on a substantial number of small entities. I certify that this final rule does not have a significant economic impact on a substantial number of small entities and, therefore, a regulatory flexibility analysis, as defined under the Regulatory Flexibility Act of 1980, is not required.

Paperwork Reduction Act

This final rule does not contain information collection requirements which are subject to Office of Management and Budget approval under the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbered programs affected by this final rule are:

- 93.173 Multipurpose Deafness and Other Communication Disorders Centers
- 93.279 Drug Abuse Research Programs
- 93.397 Cancer Centers Support

- 93.837 Heart and Vascular Diseases Research
 93.838 Lung Diseases Research
 93.839 Blood Diseases and Resources Research
 93.846 Arthritis, Musculoskeletal, and Skin Diseases Research
 93.847 Diabetes, Endocrinology, and Metabolism Research
 93.848 Digestive Diseases and Nutrition Research
 93.849 Kidney Diseases, Urology and Hematology Research
 93.855 Allergy, Immunology, and Transplantation Research
 93.856 Microbiology and Infectious Diseases Research
 93.864 Population Research
 93.865 Research for Mothers and Children
 93.866 Aging Research
 93.981 Alcohol Research Center Grants

List of Subjects

42 CFR Part 52a

Grant programs—health; Medical research.

42 CFR Part 54a

Alcohol abuse, Grant programs—health, Medical research.

Dated: July 16, 1996.

Harold Varmus,
 Director, NIH.

For the reasons set forth in the preamble, subchapter D, chapter I of title 42 of the Code of Federal Regulations is amended as set forth below.

1. Under the authority of 42 U.S.C. 216, part 54a is removed.

PART 52a—NATIONAL INSTITUTES OF HEALTH CENTER GRANTS

1a. The authority citation of part 52a is revised to read as follows:

Authority: 42 U.S.C. 216, 285a–3, 285a–6(c)(1)(E), 285a–7(c)(1)(G), 285b–4, 285c–5, 285d–6, 285e–2, 285e–3, 285f–1, 285g–5, 285g–7, 285m–3, 285n–2, 285o–2, 300cc–16.

2. Section 52a.1 is revised to read as follows:

§ 52a.1 To which programs do these regulations apply?

(a) The regulations of this part apply to grants by the National Institutes of Health and its organizational components to support the planning, establishment, strengthening or expansion, and operation of research and demonstration and/or multipurpose centers in the health fields described in this paragraph. Specifically, these regulations apply to national cancer research and demonstration centers (including payments for construction,

but not including the acquisition of land), as authorized by section 414 of the Act; national cancer research and demonstration centers with respect to breast cancer, as authorized by section 417 of the Act; national cancer research and demonstration centers with respect to prostate cancer, as authorized by section 417A of the Act; national research and demonstration centers for heart, blood vessel, lung, and blood diseases, sickle cell anemia, blood resources and pediatric cardiovascular diseases (including payments for construction, but not including the acquisition of land), as authorized by section 422 of the Act; research and training centers in diabetes mellitus and related endocrine and metabolic diseases (including digestive, kidney, and urologic diseases), and research and training centers regarding nutritional disorders, including obesity, as authorized by section 431 of the Act; multipurpose arthritis and musculoskeletal diseases centers (including payments for alteration, remodeling, improvement, expansion, and repair of existing buildings, and the provision of equipment necessary to make them suitable for use as a center, but not construction), as authorized by Section 441 of the Act; Alzheimer's disease centers, as authorized by section 445 of the Act; Claude D. Pepper Older Americans Independence Centers, as authorized by section 445A of the Act; research centers regarding chronic fatigue syndrome, as authorized by section 447 of the Act; research centers with respect to contraception and infertility, as authorized by section 452A of the Act; child health research centers, as authorized by section 452C of the Act; multipurpose deafness and other communication disorders centers (including payments for alteration, remodeling, improvement, expansion, and repair of existing buildings, and the provision of equipment necessary to make them suitable for use as a center, but not construction), as authorized by section 464C of the Act; national alcohol research centers, as authorized by section 464J of the Act; national drug abuse research centers, as authorized by section 464N of the Act; and centers for acquired immunodeficiency syndrome research (including payments for renovation and leasing of existing buildings, and the provision of equipment necessary to make them suitable for use as a center, but not construction), as authorized by section 2316 of the Act.

(b) This part does not apply to:

(1) Grants for construction (see 42 CFR part 52b), except as noted in paragraph (a) of this section;

(2) Grants covered by 42 CFR part 52 (grants for research projects); or
 (3) Grants for general research support under section 301(a)(3) of the Act (42 U.S.C. 241(a)(3)).

(c) This part also applies to cooperative agreements made to support the centers specified in paragraph (a) of this section. When a reference is made in this part to "grants," the reference shall include "cooperative agreements."

3. Section 52a.2 is amended by revising the definition of "Center" and adding definitions of the terms "Director", "Grant(s)", and "Project period" to read as follows:

§ 52a.2 Definitions.

* * * * *

Center means:

(1) For purposes of grants authorized by section 414 of the Act, an agency or institution which provides for planning and conducting basic and clinical research into, training in, and demonstration of advanced diagnostic, control, prevention and treatment methods for cancer;

(2) For purposes of grants authorized by section 417 of the Act, an agency or institution which provides for planning and conducting basic, clinical, epidemiological, psychosocial, prevention and treatment research and related activities on breast cancer;

(3) For purposes of grants authorized by section 417A of the Act, an agency or institution which provides for planning and conducting basic, clinical, epidemiological, psychosocial, prevention and control, treatment, research, and related activities on prostate cancer;

(4) For purposes of grants authorized by section 422 of the Act, an agency or institution which provides for planning and basic and clinical research into, training in, and demonstration of, management of blood resources and advanced diagnostic, prevention, and treatment methods (including emergency services) for heart, blood vessel, lung, or blood diseases including sickle cell anemia;

(5) For purposes of grants authorized by section 431 of the Act, a single institution or a consortium of cooperating institutions which conducts research, training, information programs, epidemiological studies, data collection activities and development of model programs in: diabetes mellitus and related endocrine and metabolic diseases; kidney and urologic diseases; or nutritional disorders, including obesity;

(6) For purposes of grants authorized by section 441 of the Act, a single institution or a consortium of

cooperating institutions which conducts basic and clinical research into arthritis and musculoskeletal diseases and orthopedic procedures, and provides training and information programs for health professionals and the general public;

(7) For purposes of grants authorized by section 445 of the Act, an entity (including a university medical center) which conducts basic and clinical research (including multidisciplinary research) into, training in, and demonstration of advanced diagnostic, prevention, and treatment methods for Alzheimer's disease;

(8) For purposes of grants authorized by section 445A of the Act, an entity which conducts research into the aging processes and into the diagnosis and treatment of diseases, disorders, and complications related to aging, including menopause, which includes research on the treatments, and on medical devices and other medical interventions regarding these diseases, disorders, and complications that can assist individuals in avoiding institutionalization and prolonged hospitalization and in otherwise increasing the independence of the individuals;

(9) For purposes of grants authorized by section 447 of the Act, a single institution or consortium of cooperating institutions which conducts basic and clinical research on chronic fatigue syndrome;

(10) For purposes of grants authorized by section 452A of the Act, a single institution or consortium of cooperating institutions which conducts clinical and other applied research, training programs, continuing education programs, and information programs with respect to methods of contraception and infertility;

(11) For purposes of grants authorized by section 452C of the Act, an agency or institution which conducts research with respect to child health, and gives priority to the expeditious transfer of advances from basic science to clinical applications and improving the care of infants and children;

(12) For purposes of grants authorized by section 464C of the Act, a single institution or a consortium of cooperating institutions which conducts basic and clinical research into, training in, information and continuing education programs for health professionals and the general public about, and demonstration of, advanced diagnostic, prevention, and treatment methods for disorders of hearing and other communication processes and complications resulting from these disorders;

(13) For purposes of grants authorized by section 464J of the Act, an entity engaged in long-term interdisciplinary research relating to alcoholism and other alcohol problems;

(14) For purposes of grants authorized by section 464N of the Act, an entity for interdisciplinary research relating to drug abuse and other biomedical, behavioral, and social issues related to drug abuse; or

(15) For purposes of grants authorized by section 2316 of the Act, an entity for basic and clinical research into, and training in, advanced diagnostic, prevention, and treatment methods for acquired immunodeficiency syndrome.

(16) As provided in the section of the Act authorizing the particular program or on the determination of the Director, a center may include the facilities of a single institution or a consortium of cooperating institutions and, if practical, may be part of an equitable geographical distribution of centers with proven research capabilities.

Director means the Director of NIH or the organizational component authorized to award grants to support centers under this part.

Grant(s) means, unless the context otherwise requires, an award of funds to support a center authorized under § 52a.1. The term includes cooperative agreement(s).

* * * * *

Project period means the period of time, from one to five years, specified in the notice of grant award that the NIH or the awarding component intends to support a proposed center without requiring the center to re compete for funds.

* * * * *

4. Section 52a.3 is amended by revising paragraphs (a) and (b) to read as follows:

§ 52a.3 Who is eligible to apply?

(a) Any public or private nonprofit agency, institution, or consortium of agencies is eligible to apply for a grant under sections 414, 417, 417A, 422, 445, 445A, 447, 452A, and 2316 of the Act.

(b) Any public or private nonprofit or for-profit agency, institution, or consortium of agencies is eligible to apply for a grant under sections 431, 441, 452C, 464C, 464J, and 464N of the Act.

(c) * * *

5. Section 52a.7 is revised to read as follows:

§ 52a.7 For what purposes may a grantee spend grant funds?

A grantee shall spend funds it receives under this part solely in accordance with the approved

application and budget, the authorizing legislation, the regulations of this part, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR 74.27.

6. Section 52a.8 is amended by revising the heading; revising the reference to 45 CFR part 74; adding references to 42 CFR part 50, subpart F; adding an entry for "59 FR 14508" immediately following the entry "45 CFR part 93"; removing the entry "51 FR 16958 or successor" and inserting in its place an entry "59 FR 34496"; and revising the reference to Public Health Service Policy on Humane Care and Use of Laboratory Animals to read as follows:

§ 52a.8 Other HHS regulations and policies that apply.

* * * * *

*42 CFR part 50, subpart F—*Responsibility of applicants for promoting objectivity in research for which PHS funding is sought

* * * * *

*45 CFR part 74—*Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with states, local governments and Indian tribal governments

* * * * *

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, MSC 0161, BETHESDA, MD 20892-0601 (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, MSA 7010, BETHESDA, MD 20892-7010 (301-496-9838; not a toll-free number) to obtain references to the current version and any amendments.]

Public Health Service Policy on Humane Care and Use of Laboratory Animals, Office for Protection from Research Risks, NIH (Revised September 1986). [Note: this policy is subject to change, and interested persons should contact the Office for Protection from Research Risks, NIH, Suite 3B01, 6100 Executive Boulevard, MSC 7507, Bethesda, MD 20892-7507 (301-496-

7005; not a toll-free number) to obtain references to the current version and any amendments.]

7. Section 52a.9 is revised to read as follows:

§ 52a.9 Additional conditions.

The Director may, with respect to any grant award, impose additional conditions prior to or at the time of any award when in the Director's judgment the conditions are necessary to assure the carrying out of the purposes of the award, the interests of the public health, or the conservation of grant funds.

[FR Doc. 96-26972 Filed 10-23-96; 8:45 am]

BILLING CODE 4140-01-P

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: Final rule.

SUMMARY: The National Institutes of Health (NIH) is issuing regulations governing non-National Research Service Award (NRSA) training grants awarded under sections 307(b)(3), 405(b)(1)(C), 485B(b), 2315(a)(1)(A), and 2354(a)(3)(C) of the Public Health Service (PHS) Act, as amended, and section 103(h)(2) of 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 necessary to implement other non-NRSA research training grant authorities set forth in the Public Health Service Act and the Clean Air Act.

EFFECTIVE DATE: This final rule is effective November 25, 1996.

FOR FURTHER INFORMATION CONTACT: Mr. Jerry Moore, Regulatory Affairs Officer, National Institutes of Health, 9000 Rockville Pike, Building 31, Room 1B-25, 31 Center Dr MSC 2075, Bethesda, MD 20892-2075, telephone (301) 496-4606 (not a toll-free number). For program information contact the Office of Extramural Research, National Institutes of Health, 9000 Rockville Pike, Shannon Building, Room 144, One Center Dr MSC 0152, Bethesda, MD 20892-0152, telephone (301) 496-1096 (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 codified at 42 CFR part 66. The regulations which NIH is issuing concerning training grants do not affect the NRSA Program or amend the regulations codified in part 66.

Prior to the advent of the NRSA program, the NIH institutes relied upon provisions of the PHS Act that authorized the institutes 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 (Pub. L. 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 29192) revising the 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 National Institutes of Health Revitalization Act of 1993 (Pub. L. 103-43), authorized the Director of the National Center for Human Genome Research (NCHGR), 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, as amended.

Additionally, section 2315(a)(1) of the PHS Act, as amended, 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, as amended.

NIH published a notice of proposed rulemaking (NPRM) in the Federal Register of January 24, 1995 (60 FR 4742), in which it announced its plans to issue new regulations at part 63a to govern implementation of these training grant authorities. One comment supporting the regulations was received. Consequently, except for a few minor editorial changes, the final regulations are the same as those announced in the NPRM.

The regulations 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, other than NRSA and NLM programs, with exceptions or special provisions for particular programs as necessary.

Readers of this final rule 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 final rule sets forth what training is covered by the regulations, the nature and purpose of the training, what