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

institutions are eligible to apply, how to apply, how grants are awarded, and conditions imposed on recipients. Implementation of the particular training grant programs encompassed by these regulations rests with the statutorily authorized awarding NIH components and is subject to the availability of funds for that purpose, as well as programmatic priorities determined by the awarding components.

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

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and 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.

Executive Order 12866

Executive Order 12866 requires that all regulatory actions reflect consideration of the costs and benefits they generate, and that they must 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 deemed 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 rule will 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 any information collection requirements which are subject to Office of Management and Budget (OMB) 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 (CFDA) numbered program affected by this final rule 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: July 23, 1996.

Harold Varmus,

Director, NIH.

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

PART 63a—NATIONAL INSTITUTES OF HEALTH TRAINING GRANTS

Sec.

Authority: 42 U.S.C. 216, 242*l*(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) The regulations of this part 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 the 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 the 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.*).

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 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 as 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 to support individuals for research training relating to acquired immunodeficiency syndrome (AIDS), as authorized under section 2315(a)(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, activities 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 without requiring the grantee to recompete 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 the 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 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 the following costs:

(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—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
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 change, 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 change, 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 (Revised April 1, 1994), as amended by the Addendum, dated January 24, 1995. [Note: this policy is subject to change, and interested persons should contact the Extramural Outreach and Information Resources Office (EOIRO), Office of Extramural Research, 6701 Rockledge Drive, Room 6208, MSC 7910, Bethesda, MD 20892–7910 (301–435–0714; not a toll-free number) to obtain references to the current version and any amendments. Information may also be obtained by contacting the EOIRO via its e-mail address (asknih@odrockm1.od.nih.gov) and by browsing the NIH Home Page site on the World Wide Web (http://www.nih.gov).]
''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, Rockville, MD 20852–7507 (301–496–7005; not a toll-free number) to obtain references to the current version and any amendments.]

[FR Doc. 96–26974 Filed 10–23–96; 8:45 am]
BILLING CODE 4140–01–P

42 CFR Part 65a

RIN 0925–AA03

National Institute of Environmental Health Sciences Hazardous Substances Basic Research and 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 new regulations to govern grants for research and training awarded by the National Institute of Environmental Health Sciences (NIEHS) for the purpose of understanding, assessing, and attenuating the adverse effects on human health of exposure to hazardous substances. The grants are authorized by section 311(a) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as added by section 209 of the Superfund Amendments and Reauthorization Act of 1986.

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 DRIVE MSC 2075, BETHESDA, MD 20892–2075, telephone (301–496–4606; not a toll-free number). For further information about the grant program contact: Dr. William A. Zuk, Chemical Exposures and Molecular Biology Branch, NIEHS, Division of Extramural Research and Training, 104 T. W. Alexander Drive, P.O. Box 12233, Research Triangle Park, NC 27709, telephone (919–541–1403; not a toll-free number).

SUPPLEMENTARY INFORMATION: Section 311(a) of CERCLA, enacted on October 17, 1986, authorizes the Secretary of Health and Human Services (Secretary), acting through the Director of the National Institute of Environmental Health Sciences (NIEHS) and, in consultation with the Administrator of the Environmental Protection Agency, to administer a program of grants for basic research and training directed towards understanding, assessing, and attenuating the adverse effects on human health resulting from exposure to hazardous substances. Grants made under this program are for coordinated, multi-component, interdisciplinary projects linking biomedical research with related engineering, hydrologic, and ecologic research, and concomitant training. NIH published a full description of the program in the Federal Register of November 21, 1986 (51 FR 43089), and invited the public to attend an open meeting on the program which was held on December 19, 1986. Subsequently, NIH announced its intention to issue regulations to implement this program in the ''Unified Agenda of Federal Regulations'' published in the Federal Register of October 21, 1991 (56 FR 53327), and published proposed regulations in a notice of proposed rulemaking (NPRM) in the Federal Register of March 7, 1995 (60 FR 12525). The public was given 60 days in which to comment on the proposed regulations. The NIH received one comment which supported the regulations. Except for minor editorial and clarifying changes, the final regulations are the same as those published in the NPRM.

The following statements are provided as information for the public.

The Department of Health and Human Services (HHS) 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