

- 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.]

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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

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 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 term "significant regulatory action," as defined in section 3(f) of the Order, prepublication 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 by OIRA 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. This rule merely codifies internal policies and procedures of the Federal Government currently used by the NIH to administer the NIEHS Hazardous Substances Basic Research and Training Grants program. The grants do not have a significant economic or policy impact on a broad cross-section of the public. Furthermore, this rule would only affect those qualified public and private nonprofit institutions of higher education; generators of hazardous waste; persons involved in the detection, assessment, evaluation, and treatment of hazardous substances; owners and operators of facilities at which hazardous substances are located; and state and local governments interested in participating in the program. No individual or institution is obligated to participate in the grant program.

For these same reasons, this rule will not have a significant economic impact on a substantial number of small entities and that a regulatory flexibility analysis is not required under the Regulatory Flexibility Act of 1980.

Paperwork Reduction Act

The rule does not contain information collection requirements subject to review and approval by the Office of Management and Budget (OMB) 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 rule is: 93.143.

List of Subjects in 42 CFR Part 65a

Grant programs—health; Health; Medical research; Hazardous substances.

Dated: August 8, 1996.

Harold Varmus,
Director, NIH.

For the reasons set forth in the preamble, title 42 of the Code of Federal Regulations is amended by adding a new part 65a, as follows.

PART 65a—NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES HAZARDOUS SUBSTANCES BASIC RESEARCH AND TRAINING GRANTS

Sec.

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Authority: 42 U.S.C. 216, 9660(a).

§ 65a.1 To what programs do these regulations apply?

(a) The regulations of this part apply to the award of grants to support programs for basic research and training directed towards understanding, assessing, and attenuating the adverse effects on human health resulting from exposure to hazardous substances, as authorized under section 311(a) of the Act (42 U.S.C. 9660(a)). The purpose of these programs is to carry out coordinated, multi-component, interdisciplinary research consisting of at least three or more biomedical research projects relating to hazardous substances and at least one non-biomedical research project in the fields of ecology, hydrogeology, and/or engineering, and including the training of investigators as part of the grantee's overall program.

(b) The regulations of this part also apply to cooperative agreements awarded to support the programs described 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, demonstration, and training support under the NIH Center Grants programs (see part 52a of this chapter),

(3) Research training support under traineeship programs (see parts 63 and 64a of this chapter), or

(4) Research training support under the NIH AIDS Research Loan Repayment Program authorized under section 487A of the Public Health Service Act, as amended (42 U.S.C. 288-1).

§ 65a.2 Definitions.

As used in this part:

Act means the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (42 U.S.C. 9601 et seq.).

Award or grant means a grant or cooperative agreement awarded under section 311(a) of the Act (42 U.S.C. 9660(a)).

Director means the Director of the National Institute of Environmental Health Sciences, or the Director's delegate.

HHS means the Department of Health and Human Services.

Institution of higher education means an educational institution in any state which (1) admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such a certificate, (2) is legally authorized within the state to provide a program of education beyond secondary education, (3) provides an educational program for which it awards a bachelor's degree or provides not less than a two-year program which is acceptable for full credit toward a bachelor's degree, (4) is a public or other nonprofit institution, and (5) is accredited by a nationally recognized accrediting agency or association or, if not so accredited, (i) is an institution with respect to which the Secretary of Education has determined that there is satisfactory assurance, considering the resources available to the institution, the period of time, if any, during which it has operated, the effort it is making to meet accreditation standards, and the purpose for which this determination is being made, that the institution will meet the accreditation standards of a nationally recognized accrediting agency or association within a reasonable time, or (ii) is an institution whose credits are accepted, on transfer, by not less than three institutions which are so accredited, for credit on the same

basis as if transferred from an institution so accredited. The term also includes any school which provides not less than a one-year program of training to prepare students for gainful employment in a recognized occupation and which meets the provisions of paragraphs (1), (2), (4), and (5) of this definition. The term also includes a public or nonprofit private educational institution in any state which, in lieu of the requirement in paragraph (1), admits as regular students persons who are beyond the age of compulsory school attendance in the state in which the institution is located and who meet the requirements of section 1091(d) of title 20 U.S. Code, as amended. For purposes of this definition, the Secretary of Education publishes a list of nationally recognized accrediting agencies or associations which that official determines to be reliable authority as to the quality of training offered. This list is found in the brochure, "Nationally Recognized Accrediting Agencies and Associations Criteria and Procedures for Listing by the U.S. Secretary of Education and Current List."

[Note: This brochure is subject to change, and interested persons should contact the U.S. Department of Education Office of Post-Secondary Education, Accreditation and State Liaison Division, ROB 3, 7th and D Streets, S.W., Room 37-15, Washington, DC 20202-5244 (202-708-7417; not a toll-free number) to obtain a current version of the brochure and any amendments.]

NIEHS means the National Institute of Environmental Health Sciences, an organizational component of the National Institutes of Health, as authorized under sections 401(b) and 463 of the Public Health Service Act, as amended (42 U.S.C. 281(b) and 185).

NIH means the National Institutes of Health.

Nonprofit, as applied to any agency, organization, institution, or other entity, means 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.

PHS means the Public Health Service.

Program means the activity to carry out research and training supported by a grant under this part.

Program director means the single individual designated by the grantee in the grant application and approved by the Director, who is responsible for the scientific and technical direction of the research component and the conduct of the training component under a program.

Project period means the period of time, from one to five years, specified in the notice of grant award that NIEHS intends to support a proposed program

without requiring the program awardee to recompile for funds.

Secretary means, unless the context otherwise requires, the Secretary of Health and Human Services or other official of HHS to whom the authority involved is delegated.

§ 65a.3 Who is eligible to apply for a grant?

(a) Except as otherwise prohibited by law, any public or private nonprofit institution of higher education may apply for an award under this part.

(b) Awardee institutions may carry out portions of the research or training components of an award through contracts with appropriate organizations, including:

- (1) Generators of hazardous wastes;
- (2) Persons involved in the detection, assessment, evaluation, and treatment of hazardous substances;
- (3) Owners and operators of facilities at which hazardous substances are located; and
- (4) State and local governments.

§ 65a.4 What are the program requirements?

The applicant shall include the following in its proposed program for which support is requested under this part:

(a) **Basic research component.** The program shall include three or more meritorious biomedical research projects, including epidemiologic studies relating to the study of the adverse effects of hazardous substances on human health, and at least one meritorious project involving hydrogeologic or ecologic research which shall cumulatively address:

- (1) Methods and technologies to detect hazardous substances in the environment;
- (2) Advanced techniques for the detection, assessment, and evaluation of the effects of these substances on human health;
- (3) Methods to assess the risks to human health presented by these substances; and
- (4) Basic biological, chemical, and/or physical methods to reduce the amount and toxicity of these substances.

(b) **Training component.** The program shall include the following kinds of training, as part of or in conjunction with the basic research component:

- (1) Graduate training in environmental and occupational health and safety and in public health and engineering aspects of hazardous waste control; and/or
- (2) Graduate training in the geosciences, including hydrogeology, geological engineering, geophysics,

geochemistry, and related fields, necessary to meet professional personnel needs in the public and private sectors and to carry out the purposes of the Act; and

(3) Worker training relating to handling hazardous substances, which includes short courses and continuing education for state and local health and environmental agency personnel and other personnel engaged in the handling of hazardous substances, in the management of facilities at which hazardous substances are located, and in the evaluation of the hazards to human health presented by these facilities.

§ 65a.5 How to apply.

Each institution desiring a grant under this part must submit an application at the time and in the form and manner as the Secretary may require.

§ 65a.6 How will applications be evaluated?

The Director shall evaluate applications through the officers and employees, experts, consultants, or groups engaged by the Director for that purpose, including review by the National Advisory Environmental Health Sciences Council in accordance with peer review requirements set forth in part 52h of this chapter. The Director's first level of evaluation will be for technical 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 applicant's resources available for the program, and the amount of grant funds necessary for completion of its objectives. A second level of review will be conducted by the National Advisory Environmental Health Sciences Council.

§ 65a.7 Awards.

Criteria. Within the limits of available funds, the Director may award grants to carry out those programs which:

- (a) Are determined by the Director to be meritorious; and
- (b) In the judgment of the Director, best promote the purposes of the grant program, as authorized under section 311(a) of the Act and the regulations of this part, and best address program priorities.

§ 65a.8 How long does grant support last?

(a) The notice of grant award specifies how long NIEHS intends to support the project without requiring the grantee to recompile for funds. This period, called the project period, may be for 1-5 years.

(b) Generally, the grant will initially be for one year, and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application at the time and in the form and manner as 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 a determination by the Director 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 Director, provided a continuation award is made. If at any time during a budget period it becomes apparent to the Director 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 Director may adjust the amounts awarded by withdrawing the excess.

§ 65a.9 What are the terms and conditions of awards?

In addition to being subject to other applicable regulations (see § 65a.11), grants awarded under this part are subject to the following terms and conditions:

(a) *Material changes.* Except as otherwise provided by 45 CFR 74.25, the grantee may not materially change the quality, nature, scope, or duration of the program unless the written approval of the Director is obtained prior to the change.

(b) *Additional conditions.* The Director may impose additional conditions prior to the award of any grant under this part if it is determined by the Director that the conditions are necessary 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.

§ 65a.10 For what purposes may grant funds be spent?

A grantee shall spend 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 award, and the applicable cost principles prescribed in 45 CFR 74.27.

§ 65a.11 Other HHS regulations and policies that apply.

Several other HHS regulations and policies apply to awards under 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
- 42 CFR part 50, subpart F—Responsibility of applicants for promoting objectivity in research for which PHS funding is sought
- 42 CFR part 52h—Scientific peer review of research grant applications and research and development contract projects
- 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)
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45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

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"Public Health service Policy on Humane Care and Use of Laboratory animals," Office for Protection from Research Risks, HHS (Revised September 1986).

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