

4039 Eighth Zone. The eighth zone includes all units of area outside the seventh zone.

4040 Zoned Rates

Except as provided in section 4050, rates according to zone apply for zone-rated mail sent between Postal Service facilities including armed forces post offices, wherever located.

4050 APO/FPO Mail

4051 General. Except as provided in section 4052, the rates of postage for zone-rated mail transported between the United States, or the possessions or territories of the United States, on the one hand, and Army, Air Force and Fleet Post Offices on the other, or among the latter, shall be the applicable zone rates for mail between the place of mailing or delivery and the city of the postmaster serving the Army, Air Force or Fleet Post Office concerned.

4052 Transit Mail. The rates of postage for zone-rated mail which is mailed at or addressed to an armed forces post office and which is transported directly to or from armed forces post offices at the expense of the Department of Defense, without transiting any of the 48 contiguous states (including the District of Columbia), shall be the applicable local zone rate; provided, however, that if the distance from the place of mailing to the embarkation point or the distance from the point of debarkation to the place of delivery is greater than the local zone for such mail, postage shall be assessed on the basis of the distance from the place of mailing to the embarkation point or the distance from the point of debarkation to the place of delivery of such mail, as the case may be. The word "transiting" does not include enroute transfers at coastal gateway cities which are necessary to transport military mail directly between military post offices.

5000 PRIVACY OF MAIL

5010 First-Class and Express Mail

Matter mailed as First-Class Mail or Express Mail shall be treated as mail which is sealed against postal inspection and shall not be opened except as authorized by law.

5020 All Other Mail

Matter not paid at First-Class Mail or Express Mail rates must be wrapped or secured in the manner prescribed by the Postal Service so that the contents may be examined. Mailing of sealed items as other than First-Class Mail or Express Mail is considered consent by the sender to the postal inspection of the contents.

6000 MAILABLE MATTER

6010 General

Mailable matter is any matter which:

- Is not mailed in contravention of 39 U.S.C. Chapter 30, or of 17 U.S.C. 109;
- While in the custody of the Postal Service is not likely to become damaged itself, to damage other pieces of mail, to cause injury to Postal Service employees or to damage Postal Service property; and
- Is not mailed contrary to any special conditions or limitations placed on transportation or movement of certain

articles, when imposed under law by the U.S. Department of the Treasury; U.S. Department of Agriculture; U.S. Department of Commerce; U.S. Department of Health and Human Services, U.S. Department of Transportation; and any other Federal department or agency having legal jurisdiction.

6020 Minimum Size Standards

The following minimum size standards apply to all mailable matter:

- All items must be at least 0.007 inches thick, and
- all items, other than keys and identification devices, which are 0.25 inch thick or less must be
 - rectangular in shape,
 - at least 3.5 inches in width, and
 - at least 5 inches in length.

6030 Maximum Size and Weight Standards

Where applicable, the maximum size and weight standards for each class of mail are set forth in sections 130, 230, 330 and 430. Additional limitations may be applicable to specific subclasses, and rate and discount categories as provided in the eligibility provisions for each subclass or category.

* * * * *

5. In Appendix A under Rate Schedules, the table First-Class Mail Rate Schedule 221, Letters and Sealed Parcels is amended by removing under "Regular, Piece" the entry for Courtesy Envelope Mail.

Cyril J. Pittack,
Acting Secretary.

[FR Doc. 96-27247 Filed 10-23-96; 8:45 am]

BILLING CODE 7710-FW-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 52

RIN 0905-AC02

Grants for Research Projects

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Final rule.

SUMMARY: The National Institutes of Health (NIH) is amending the regulations governing Public Health Service (PHS) grants for research projects to: accommodate changes necessitated by enactment of various statutes governing research project grant programs administered by the PHS; updated references to statutes and regulations; and cover all research project grant programs administered by the PHS, except for grants for health services research, demonstration, and evaluation projects administered by the Agency for Health Care Policy and

Research (AHCPR), so the regulations will not have to be amended each time a new research project grant program is established by statute or administrative action.

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 1B05, 31 CENTER DR MSC 2075, BETHESDA, MD 20892-2075, telephone (301) 496-4606 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The regulations at 42 CFR part 52 governing PHS grants for research projects were last amended on September 27, 1984 (49 FR 38110). Since then, Congress enacted a number of statutes establishing research grant programs similar to those listed in § 52.1 of the current regulation. In the past, new statutory authority would have been implemented by adding the new programs to the list of programs in § 52.1.

However, after considering the long list of programs to be added and the very limited number of substantive changes necessitated by the new statutes, the NIH is deleting the listing of research project grant programs in § 52.1, and references to that listing in other sections. The regulations are amended to apply to all research project grant programs administered by the PHS, except for grants for health services research, demonstration, and evaluation projects administered by the AHCPR. Thus, in the future it will not be necessary to include a long list of programs in the regulations or to go through the lengthy process of amending the regulations in order for them to apply to a newly established program.

The PHS and/or its components that award research project grants will periodically publish a list of all the research project grant programs to which the regulations apply and the applicability of the regulations to new programs will be announced as PHS components initiate those programs. Under § 52.1, the amended regulations clearly apply to all research project grants administered by the PHS except for the AHCPR grants referenced above. Thus, the lists described above are provided for the convenience of interested members of the public, rather than serving as a substantive notice of the applicability of the regulations. A list of the current research project grant authorities implemented by the regulations follows:

(1) Research into the cause, diagnosis, treatment, control, or prevention of the

physical or mental diseases, injuries, or impairments to human life, as authorized by sections 301, 303 and related provisions of the Public Health Service Act (Act) (42 U.S.C. 241, 242a);

(2) Research into the prevention and control of childhood lead poisoning, as authorized under section 301 of the Act (42 U.S.C. 241);

(3) Epidemiologic studies, and state-based research capacity building projects for the prevention of primary and secondary disabilities, as authorized under section 301 of the Act (42 U.S.C. 241);

(4) Ecological and epidemiologic research studies in Lyme disease, including disease surveillance, development and evaluation of prevention and control studies, and development of improved diagnostic tests, as authorized under section 301 of the Act (42 U.S.C. 241);

(5) Investigation to identify strategies for prevention of childhood deaths from diarrhea, as authorized under sections 301 and 317(k)(3) of the Act (42 U.S.C. 241, 247(k)(3));

(6) HIV/AIDS surveillance, HIV serosurveillance surveys and studies, and epidemiologic research studies of AIDS and HIV infection, as authorized under sections 301 and 317(k)(3) of the Act (42 U.S.C. 241 and 247b(k)(3));

(7) Surveillance and epidemiologic studies for the prevention of infectious diseases and injuries in children in child day care settings, as authorized under sections 301, 317(k)(3), and 391 of the Act (42 U.S.C. 241, 247b(k)(3), 280b);

(8) Research for the development of knowledge and approaches to the epidemiology, etiology, diagnosis, treatment, control and prevention of narcotic addiction and intravenous (IV)-related AIDS and drug abuse, as authorized under sections 301 and 405 of the Act (42 U.S.C. 241, 284);

(9) Research into prevention and control of tuberculosis, especially research concerning strains of tuberculosis resistant to drugs and research concerning cases of tuberculosis that affect certain populations, as authorized by section 317(k) of the Act (42 U.S.C. 247b(k));

(10) Injury prevention and control research, as authorized by section 391 of the Act (42 U.S.C. 280b);

(11) Research on osteoporosis, paget's disease and related bone disorders, as authorized by section 409A of the Act (42 U.S.C. 284e).

(12) Biomedical research in areas relating to Alzheimer's disease and related dementias, as authorized by section 445B of the Act (42 U.S.C. 285e-4);

(13) Research relating to medical rehabilitation, as authorized by section 452 of the Act (42 U.S.C. 285g-4);

(14) Research on clinical and health services on eye care and diabetes, as authorized by section 456 of the Act (42 U.S.C. 285i-1);

(15) Research on multiple sclerosis, especially research on the effects of genetics and hormonal changes on the progress of the disease, as authorized by section 460 of the Act (42 U.S.C. 285j-3);

(16) Research on the social, behavioral, and biomedical etiology, mental and physical health consequences, and social and economic consequences of alcohol abuse and alcoholism, as authorized by section 464H of the Act (42 U.S.C. 285n);

(17) Health services research activities with respect to the prevention of alcohol abuse and treatment of alcoholism, as authorized by section 464H of the Act (42 U.S.C. 285n) and defined in section 409 of the Act (42 U.S.C. 284d);

(18) Research under the Medication Development Program to encourage and promote the development and use of medications to treat drug addiction; and to collect, analyze, and disseminate data, as authorized by section 464P of the Act (42 U.S.C. 285o-4);

(19) Research on health related educational technologies, medical library science and related activities, and for the development or dissemination of new knowledge, techniques, systems, and equipment for processing, storing, retrieving, and distributing information pertaining to health sciences, as authorized by section 473 of the Act (42 U.S.C. 286b-4);

(20) Research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population, as authorized by section 1004 of the Act (42 U.S.C. 300a-2);

(21) Research on the causes, consequences and approaches of coping with adolescent sexual relations, contraceptive use, pregnancy, and parenthood, as authorized by section 2008 of the Act (42 U.S.C. 300z-7);

(22) Research relating to the evaluation of drug treatments for AIDS not approved by the Commissioner of Food and Drugs, as authorized by section 2314 of the Act (42 U.S.C. 300cc-14);

(23) International research relating to the development and evaluation of vaccines and treatments for AIDS, as authorized by section 2315 of the Act (42 U.S.C. 300cc-15);

(24) Long-term research into treatments for AIDS, as authorized by

section 2320 of the Act (42 U.S.C. 300cc-20);

(25) Research relating to AIDS conducted outside the United States by qualified foreign professionals and collaborative research involving American and foreign participants, as authorized in section 2354 of the Act (42 U.S.C. 300cc-41);

(26) Basic research to identify, characterize, and quantify risks to human health from air pollutants, as authorized by section 103 of the Clean Air Act (42 U.S.C. 7403);

(27) Electronic product radiation control research programs designed to protect the public health and safety from electronic product radiation, as authorized by section 532 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ii);

(28) Research into areas where a microgravity environment may contribute to significant progress in the understanding and treatment of diseases and other medical conditions, as authorized by section 603 of the National Aeronautics and Space Administration Authorization Act, Fiscal Year 1993 (42 U.S.C. 2487b);

(29) Support for radiation studies and research, as authorized under section 301 of the Act (42 U.S.C. 241) and by section 20(a) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 669(a));

(30) Research on occupational safety and health problems in industry, as authorized by section 20(a) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 669a) and section 501 of the Federal Coal Mine Health and Safety Act of 1969 (30 U.S.C. 951); and

(31) Research to stimulate health-related technological innovation especially through the use of small business, minority and disadvantaged firms and increased private sector commercialization of innovations derived from Federal research and development, as authorized under section 301 of the Act, (42 U.S.C. 241), in accordance with the procedures prescribed pursuant to the Small Business Innovation Development Act of 1982 (15 U.S.C. 638).

A more detailed listing of the programs implemented by this rule, as listed in the Catalog of Federal Domestic Assistance, appears at the end of this preamble.

In addition to the actions noted above, NIH is limiting the citation of authority for issuance of the regulations to the Secretary's general statutory authority for the issuance of regulations set forth in section 215 of the PHS Act, rather than citing the statutory authority for each research project grant program.

The latter provisions do not require or explicitly authorize the issuance of regulations and thus 1 CFR part 21, subpart B, does not require inclusion of those statutes in the authority citation.

The regulations are amended by making minor changes required by new statutory authority, simplifying the language in §§ 52.2–52.4 and 52.6, updating PHS Act section numbers referenced in part 52 as necessitated by enactment of legislation, and updating the listing of HHS policies and regulations in § 52.8. The NIH announced its plans to make these changes in the notice of proposed rulemaking (NPRM) that it published in the Federal Register of August 2, 1994 (59 FR 39312). The NIH received no comments concerning the NPRM. Thus, no substantive changes were made to the proposed regulations. However, language was added to the preamble and § 52.1(a) to explicitly indicate that part 52 does not apply to grants for health services research, demonstration, and evaluation projects administered by the AHCPR.

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 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 definition of the term “significant regulatory action” contained in section 3(f) of the Order, pre-publication review by the Office of the 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. Because of the nonsubstantive nature of the

amendments in this rule, the Secretary certifies 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 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 programs affected by the regulations are:

- 93.113—Biological Response to Environmental Health Hazards
- 93.114—Applied Toxicological Research and Testing
- 93.115—Biometry and Risk Estimation—Health Risks from Environmental Exposures
- 93.118—Acquired Immunodeficiency Syndrome (AIDS) Activity
- 93.121—Oral Diseases and Disorders Research
- 93.135—Centers for Research and Demonstration for Health Promotion and Disease Prevention
- 93.136—Injury Control Research Projects
- 93.154—Special International Postdoctoral Research Program in Acquired Immunodeficiency Syndrome
- 93.173—Biological Research Related to Deafness and Communicative Disorders
- 93.184—Disabilities Prevention
- 93.198—Biological Models and Materials Resources Program
- 93.242—Mental Health Research Grants
- 93.262—Occupational Safety and Health Research Grants
- 93.271—Alcohol Scientist Development Award; Scientist Development Award for Clinicians; and Research Scientist Award
- 93.273—Alcohol Research Programs
- 93.277—Drug Abuse Scientist Development Award for Clinicians, and Scientist Development Awards
- 93.279—Drug Abuse Research Programs
- 93.281—Mental Health Research Scientist Development Award, Research Scientist Development Award for Clinicians, and Research Scientist Award
- 93.283—Centers for Disease Control—Investigation and Technical Assistance
- 93.306—Comparative Medicine Program (formerly called Laboratory Animal Sciences and Primate Research)
- 93.333—General Clinical Research Centers
- 93.361—Nursing Research
- 93.371—Biomedical Research Technology
- 93.389—Research Centers in Minority Institutions
- 93.390—Academic Research Enhancement Award
- 93.393—Cancer Cause and Prevention Research

- 93.394—Cancer Detection and Diagnosis Research
- 93.395—Cancer Treatment Research
- 93.396—Cancer Biology Research
- 93.821—Biophysics and Physiological Sciences Research
- 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 Metabolic Research
- 93.848—Digestive Diseases and Nutrition Research
- 93.849—Kidney Diseases, Urology and Hematology Research
- 93.853—Clinical Research Related to Neurological Disorders
- 93.854—Biological Basis Research in the Neurosciences
- 93.855—Allergy, Immunology, and Transplantation Research
- 93.856—Microbiology and Infectious Diseases Research
- 93.859—Pharmacological Sciences
- 93.862—Genetics Research
- 93.863—Cellular and Molecular Basis of Disease Research
- 93.864—Population Research
- 93.865—Research for Mothers and Children
- 93.866—Aging Research
- 93.867—Vision Research
- 93.879—Medical Library Assistance
- 93.929—Center for Medical Rehabilitation Research
- 93.934—Fogarty International Research Collaboration Award
- 93.939—Blood Diseases and Resources Research
- 93.941—HIV Demonstration, Research, Public and Professional Education Projects
- 93.942—Research, Treatment and Education Programs on Lyme Disease in the United States
- 93.943—Epidemiologic Research Studies of Acquired Immunodeficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV) Infection in Selected Population Groups
- 93.947—Tuberculosis Demonstration, Research, Public and Professional Education

List of Subjects in 42 CFR Part 52

Grant programs—Health; Medical research; Occupational safety and health.

Dated: July 25, 1996.

Harold Varmus,
Director, NIH.

For reasons set out in the preamble, part 52 of title 42 of the Code of Federal Regulations is amended as set forth below.

PART 52—GRANTS FOR RESEARCH PROJECTS

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

Authority: 42 U.S.C. 216.

2. Section 52.1 is revised to read as follows:

§ 52.1 To which programs do these regulations apply?

(a) *General.* The regulations of this part apply to all health-related research project grants administered by the PHS or its components, except for grants for health services research, demonstration, and evaluation projects administered by the Agency for Health Care Policy and Research. These regulations do not apply to research grants that are not for the support of an identified research project (sometimes referred to as general research support grants), grants for the construction or operation of research facilities, grants for prevention or educational programs, demonstration grants, traineeships, training grants, or to the support of research training under the National Research Service Awards program.

(b) *Specific programs covered.* From time to time the Secretary will publish a list of the research project grant programs covered by this part. The list is for informational purposes only and is not intended to restrict the statement of applicability in paragraph (a) of this section. In addition, information on particular research project grant programs, including applications and instructions, may be obtained from the component of the PHS that administers the program.

3. Section 52.2 is revised to read as follows:

§ 52.2 Definitions.

As used in this part:

Act means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*).

Grantee means the institution, organization, individual or other person designated in the grant award document as the responsible legal entity to whom a grant is awarded under this part. The term shall also mean the recipient of a cooperative agreement awarded under this part.

HHS means the Department of Health and Human Services.

Principal investigator means a single individual designated by the grantee in the grant application and approved by the Secretary, who is responsible for the scientific and technical direction of the project.

Project means the particular activity for which funding is sought under this part as described in the application for grant award.

Public Health Service and *PHS* means the operating division of the Department that consists of the Agency for Health Care Policy and Research, the Centers

for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, the Office of the Assistant Secretary for Health, the Substance Abuse and Mental Health Administration, and the Agency for Toxic Substances and Disease Registry.

Research means a systematic investigation, study or experiment designed to contribute to general knowledge relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanisms relating to, the biological functions, diseases, or related matters to be studied.

Secretary means the Secretary of HHS and any other officer or employee of the HHS to whom the authority involved may be delegated.

4. Section 52.3 is revised to read as follows:

§ 52.3 Who is eligible to apply for a grant?

(a) *Persons eligible.* Any individual, corporation, public or private institution or agency, or other legal entity shall be eligible for a grant award, except:

(1) An individual or entity which is otherwise ineligible for an award under applicable law or regulation;

(2) Federal agencies or institutions, unless specifically authorized by law to receive the grant; or

(3) Individuals, corporations, institutions, agencies, and other entities during the period they are debarred or suspended from eligibility for Federal financial assistance (see 45 CFR part 76).

(b) *Permissible activities within research projects.* Any project found by the Secretary to be a research project within the meaning of this part shall be eligible for a grant award. Eligible projects may consist of laboratory, clinical, population, field, statistical, basic, applied or other types of investigations, studies or experiments, or combinations thereof, and may either be limited to one, or a particular aspect of a problem or subject, or may consist of two or more related problems or subjects for concurrent or consecutive investigation and involving multiple disciplines, facilities and resources.

(c) *Preferences.* In the award of grants for international research relating to the development and evaluation of vaccines and treatments for AIDS under section 2315 of the Act, preference shall be given to:

(1) Activities conducted by, or in cooperation with, the World Health Organization, and

(2) With respect to activities in the Western Hemisphere, activities conducted by, or in cooperation with, the Pan American Health Organization or the World Health Organization.

5. Section 52.4 is revised to read as follows:

§ 52.4 How to apply for a grant.

Each institution interested in applying for a grant under this part must submit an application at such time and in such form and manner as the Secretary may prescribe.

6. Section 52.6 is amended as follows:

In paragraph (a) the first sentence is revised to read as set forth below; paragraphs (b), (c), (d) and (e) are redesignated (c), (d), (e) and (f), respectively; new paragraph (b) is added; and newly designated paragraphs (c)(2) and (d) are revised to read as follows:

§ 52.6 Grant awards.

(a) Within the limits of funds available for that purpose, the Secretary will award a grant to those applicants whose approved projects will in the Secretary's judgment best promote the purposes of the statute authorizing the grant and the regulations of this part. * * *

(b) *Evaluation of unapproved drug treatments for AIDS.* Grants under section 2314 of the Act to support research relating to the evaluation of drug treatments for AIDS not approved by the Commissioner of Food and Drugs, shall be subject to appropriate scientific and ethical guidelines established by the Secretary for each project, pursuant to section 2314(c) of the Act. In order to receive a grant, the applicant must agree to comply with those guidelines.

(c) *Notice of grant award.*

(1) * * *

(2) 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 an application at the time and in the form and manner as the Secretary may prescribe to have support continued for each subsequent year.

(3) * * *

(d) *Multiple or concurrent awards.* Whenever a research project involves a number of different but related problems, activities or disciplines which require evaluation by different groups, or whenever support for a project could be more effectively administered by separate handling of separate aspects of the project, the Secretary may evaluate, approve and make awards pursuant to two or more concurrent applications, each dealing

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