

governing center grants to reflect their applicability to several new grant programs, including research on autism, Alzheimer's disease, fragile X disease, and minority health disparities and other types of health disparities.

**EFFECTIVE DATE:** This final rule is effective 30 days from the date of publication.

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**SUPPLEMENTARY INFORMATION:** On October 17, 2000, the United States Congress enacted the Children's Health Act of 2000 (Public Law 106-310). Section 101 of Public Law 106-310 amended the PHS Act by adding a new section 409C (42 U.S.C. 284g) concerning research on autism. Section 409C authorizes the Director of the National Institutes of Health, through the Director of the National Institute of Mental Health, to make awards of grants and contracts to public or nonprofit private entities to pay all or part of the costs of planning, establishing, improving, and providing basic operating support for centers of excellence regarding research on autism.

On November 13, 2002, the United States Congress enacted the Public Health Improvement Act (Public Law 106-505). Section 801 of Public Law 106-505 amended the PHS Act by adding a new section 445I (42 U.S.C. 285e-10a) concerning Alzheimer's clinical research and training awards. More specifically, section 445I authorizes the Director of the National Institute on Aging to establish and maintain a program to enhance and promote the translation of new scientific knowledge into clinical practice related to the diagnosis, care, and treatment of individuals with Alzheimer's disease. Amounts made available under the program must be directed to the support of promising clinicians through awards for research, study, and practice at centers of excellence in Alzheimer's disease research and treatment in environments of demonstrated excellence in neuroscience, neurobiology, geriatric medicine, and psychiatry.

Additionally, section 201 of Public Law 106-310 amended the PHS Act by adding a new section 452E (42 U.S.C. 285g-9) concerning research on the disease known as fragile X. Section 452E authorizes the Director of the National Institute of Child Health and

Human Development to make grants or enter into contracts for the development and operation of centers to conduct research for the purposes of improving the diagnosis and treatment of, and finding the cure for, fragile X.

On November 22, 2000, the United States Congress enacted the Minority Health and Health Disparities Research and Education Act of 2000 (Public Law 106-525). Section 102 of Public Law 106-525 amended the PHS Act by adding a new section 485F (42 U.S.C. 287c-32) concerning centers for minority health and health disparities related-research, education, and training. Section 485F authorizes the Director of the National Center on Minority Health and Health Disparities to make awards of grants or contracts to designated biomedical and behavioral research institutions or consortia for the purpose of assisting the institutions in supporting programs of excellence in biomedical and behavioral research training for individuals who are members of minority health disparity populations or other health disparity populations. The grants must be expended to train members of minority health disparity populations or other health disparity populations as professionals in the area of biomedical or behavioral research or both; or to expand, remodel, renovate, or alter existing research facilities or construct new research facilities for the purpose of conducting minority health disparities research and other health disparities research.

We are amending § 52a.1, § 52a.2, and § 52a.3 of the regulations governing NIH center grants to reflect these new authorities. Additionally, we are amending § 52a.8 to update the organizational reference for the Public Health Service Policy on Humane Care and Use of Laboratory Animals.

We announced our plans to amend the current regulations in a notice of proposed rulemaking (NPRM) published in the **Federal Register**, November 12, 2002 (67 FR 68548-68551). The NPRM provided for a sixty-day comment period. We received no comments. Consequently, except for various editorial changes, the final rule is the same as the proposed rule published in November 2002.

We provide the following information for the public.

#### **Executive Order 12866**

Executive Order 12866, Regulatory Planning and Review, 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, review by the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) prior to publication is necessary. The OIRA reviewed this rule under Executive Order 12866 and deemed it not significant.

#### **Regulatory Flexibility Act**

The Regulatory Flexibility Act (5 U.S.C. chapter 6) requires that regulatory proposals be analyzed to determine whether they create a significant impact on a substantial number of small entities. The Secretary certifies that this rule will not have any such impact.

#### **Executive Order 13132**

Executive Order 13132, Federalism, requires that Federal agencies consult with State and local government officials in the development of regulatory policies with federalism implications. The NIH Director reviewed this rule as required under the Order and determined that it does not have any federalism implications. The Secretary certifies that the rule will not have an effect on the States or on the distribution of power and responsibilities among various levels of government.

#### **Paperwork Reduction Act**

This rule does not contain any information collection requirements that are subject to OMB approval under the Paperwork Reduction Act of 1995, as amended (44 U.S.C. chapter 35).

#### **Catalogue of Federal Domestic Assistance**

The Catalogue of Federal Domestic Assistance (CFDA) numbered programs affected by this rule are:

- 93.173 Multipurpose Deafness and Other Communication Disorders Centers
- 93.242 Mental Health Research Grants
- 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