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108TH CONGRESS
2D SESSION

# H. R. 4779

To amend the Public Health Service Act to provide for clinical research support grants, clinical research infrastructure grants, and a demonstration program on partnerships in clinical research, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

JULY 8, 2004

Mr. WELDON of Florida (for himself and Mr. DOYLE) introduced the following bill; which was referred to the Committee on Energy and Commerce

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# A BILL

To amend the Public Health Service Act to provide for clinical research support grants, clinical research infrastructure grants, and a demonstration program on partnerships in clinical research, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Clinical Research Act of 2004''.

**SEC. 2. FINDINGS.**

The Congress finds the following:

(1) Strong academic health centers are essential to a vigorous clinical research enterprise.

(2) Breakthroughs in basic biomedical sciences over the past 5 decades have provided an unprecedented supply of information for improving human health and preventing disease.

(3) Translating the information gained through these basic discoveries into knowledge that will impact clinical practice and ultimately human health requires strong clinical research institutions.

(4) Without a sound infrastructure to accomplish this translation in a systematic and coherent way, the sum of data and information produced by the basic science enterprise will not result in tangible public benefit.

(5) The clinical research environment is increasingly encumbered by facility decay, incompatible databases, shortage of qualified investigators, rising costs, inadequate funding, and mounting unreimbursed regulatory burdens such as human subject research protections and additional record-keeping requirements under the Health Insurance Portability and Accountability Act of 1996.

**SEC. 3. DEFINITIONS.**

In this Act:

(1) The term ''Director'' means the Director of the National Institutes of Health.

(2) The term ''eligible academic health center'' means—

(A) an academic institution that receives an annual average of not less than $20,000,000 in grant funds from the Department of Defense, the Department of Veterans Affairs, and the Department of Health and Human Services for basic, applied, or clinical biomedical or behavioral research in the fields of dentistry, medicine, and nursing; or

(B) a consortium of such academic institutions.

(3) The term ''Secretary'' means the Secretary of Health and Human Services.

**SEC. 4. CLINICAL RESEARCH SUPPORT GRANTS.**

(a) AUTHORIZATION.—For the purposes described in subsection (b), the Director shall make a clinical research support grant in the amount determined under subsection (c) to each eligible academic health center that submits an application in accordance with this section.

(b) PURPOSE.—A funding agreement for a grant under this section is that the eligible academic health cen-

ter involved will use the grant only for the following purposes:

(1) To defray the costs of unfunded Federal requirements for the protection of human research subjects, including the costs of complying with the Health Insurance Portability and Accountability Act of 1996 (Pub. Law 104–191) and maintaining institutional review boards.

(2) To support activities leading to innovative ways to meet the requirements described in paragraph (1) in an efficient and cost effective manner.

(c) ALLOCATION.—Of the amount appropriated to carry out this section for a fiscal year, the Director shall allocate such appropriated amount among the eligible academic health centers receiving a grant under this section in an amount that bears the same relation to such appropriated amount as the investment in clinical research of the grantee involved bears to the total investment in clinical research of all grantees under this section.

(d) APPLICATIONS.—To seek a grant under this section, an eligible academic health center shall submit an application to the Director in such manner, at such time, and containing such information and assurances as the Director may require.

(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $40,000,000 for each of the fiscal years 2005 through 2009.

**SEC. 5. CLINICAL RESEARCH INFRASTRUCTURE GRANTS.**

(a) AUTHORIZATION.—The Director may make clinical research infrastructure grants on a competitive basis to eligible academic health centers.

(b) USE OF FUNDS.—The Director may not make a grant to an eligible academic health center under this section unless the center agrees to use the grant only for the following:

(1) Infrastructure that is necessary to facilitate the transfer of new understandings of disease mechanisms gained in the laboratory into the development of new methodologies for diagnosis, therapy, and prevention.

(2) The initial testing of human subjects.

(3) Addressing the many obstacles impeding the expeditious application of new science, such as—

(A) a lack of up-to-date information technology systems;

(B) incompatible databases;

(C) the need for training and mentoring required for increasing the supply of qualified clinical investigators; and

(D) a shortage of willing participants.

(c) APPLICATIONS.—To seek a grant under this section, an eligible academic health center shall submit an application to the Director in such manner, at such time, and containing such information and assurances as the Director may require.

(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $125,000,000 for each of fiscal years 2005 through 2009.

**SEC. 6. DEMONSTRATION PROGRAM ON PARTNERSHIPS IN CLINICAL RESEARCH.**

(a) GRANTS.—The Secretary may make grants to not more than 5 eligible academic health centers to form partnerships between the center involved and health care providers for carrying out clinical human subject research for the purpose of demonstrating how academic research centers may collaborate with the practicing health care community in such research.

(b) MAXIMUM AMOUNT.—The Secretary may not make a grant to any eligible academic health center under this section in an amount that is greater than $5,000,000.

(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $25,000,000 for the period of fiscal years 2005 through 2009.

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