109TH CONGRESS
1ST SESSION

# S. 1543

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 SENATE OF THE UNITED STATES

JULY 28, 2005

Mr. SANTORUM introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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# A BILL

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 2005''.

**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) The enhancement of clinical research career programs and opportunity will sustain the momentum of the discovery, development, and delivery of important health advances.

(5) 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.

(6) The clinical research environment is increasingly encumbered by 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) CLINICAL RESEARCH.—The term ''clinical research'' means—

(A) patient-oriented clinical research conducted with human subjects;

(B) research on the causes and consequences of disease in human populations involving material of human origin (such as tissue specimens and cognitive phenomena) for which an investigator or colleague directly interacts with human subjects in an outpatient or inpatient setting to clarify a problem in human physiology, pathophysiology or disease;

(C) epidemiologic or behavioral studies;

(D) outcomes research;

(E) health services research; or

(F) development of new technologies, therapeutic interventions, or clinical trials.

(2) DIRECTOR.—The term ''Director'' means the Director of the National Institutes of Health.

(3) ELIGIBLE ACADEMIC HEALTH CENTER.—The term ''eligible academic health center'' means

an academic institution and an affiliated teaching hospital, a teaching hospital, an independent research institute, or a consortium of research institutions which conduct clinical research and receive funds from the Department of Health and Human Services for basic, applied, or clinical biomedical or behavioral research in the fields of dentistry, medicine, or nursing.

(4) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

**SEC. 4. CLINICAL INVESTIGATOR ADVANCEMENT GRANTS.**

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

(b) PURPOSES.—A grant under this section to an eligible academic health center shall be used only for the following purposes:

(1) To establish career development programs for new and mid-level clinician-investigators who are fully committed to academic clinical research careers.

(2) To support the translation of basic science to patient care by implementing and conducting all aspects of their clinical research mission.

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

(c) CAREER DEVELOPMENT PROGRAMS.—

(1) USE OF FUNDS.—In implementing a career development program under subsection (b)(1), the Director may conduct or support activities to provide financial assistance and other support to—

(A) young clinical researchers receiving peer-reviewed grants who wish to make the transition to research independence;

(B) experienced scientists who wish to broaden their scientific capabilities; and

(C) other medical personnel who are critical to the conduct of clinical research activities.

(2) SALARY CAP.—Notwithstanding paragraph (1), no funds under this section may be used to increase the rate of pay of an individual to a rate greater than the rate of basic pay for level I of the Executive Schedule.

(d) 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 eligible grantees under this section.

(e) 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.

(f) REPORTS.—The Director shall require each recipient of a grant under this section to submit an annual report to the Director detailing how the recipient has used the grant to meet the purposes described in subsection (b).

(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $40,000,000 for each of the fiscal years 2006 through 2010.

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

(a) AUTHORIZATION.—The Director shall 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 sec-

tion unless the center agrees to use the grant only for the following:

(1) Fostering the use of information technology to facilitate the transformation of basic research findings on disease mechanisms into the development of new methodologies for diagnosis, therapy, and prevention.

(2) To devise, deploy, and support new technologies that facilitate the clinical investigators' ability to—

(A) improve the safety of human subjects in clinical research;

(B) ensure the confidentiality of research data; and

(C) streamline the regulatory processes to ensure better compliance for clinical research.

(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) a lack of connectivity between academic health centers, teaching hospitals, and independent research institutes;

(D) the absence of a coordinated strategy to enhance public understanding of, support for, and participation in clinical research; and

(E) the underrepresentation of some populations in clinical research.

(4) Sharing clinical research infrastructure across academic health centers to enable and facilitate cross-center clinical research collaborations.

(c) REPORTS.—The Director shall require each recipient of a grant under this section to submit an annual report to the Director detailing how the recipient has used the grant to meet the objectives described in subsection (b).

(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 $125,000,000 for each of fiscal years 2006 through 2010.

**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 part-

nerships 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) 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 $25,000,000 for the period of fiscal years 2006 through 2010.

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