

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.

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Clinical Research Act
5 of 2005”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds the following:

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

3 (2) Breakthroughs in basic biomedical sciences
4 over the past 5 decades have provided an unprece-
5 dented supply of information for improving human
6 health and preventing disease.

7 (3) Translating the information gained through
8 these basic discoveries into knowledge that will im-
9 pact clinical practice and ultimately human health
10 requires strong clinical research institutions.

11 (4) The enhancement of clinical research career
12 programs and opportunity will sustain the momen-
13 tum of the discovery, development, and delivery of
14 important health advances.

15 (5) Without a sound infrastructure to accom-
16 plish this translation in a systematic and coherent
17 way, the sum of data and information produced by
18 the basic science enterprise will not result in tangible
19 public benefit.

20 (6) The clinical research environment is in-
21 creasingly encumbered by incompatible databases,
22 shortage of qualified investigators, rising costs, inad-
23 equate funding, and mounting unreimbursed regu-
24 latory burdens such as human subject research pro-
25 tections and additional record-keeping requirements

1 under the Health Insurance Portability and Ac-
2 countability Act of 1996.

3 **SEC. 3. DEFINITIONS.**

4 In this Act:

5 (1) CLINICAL RESEARCH.—The term “clinical
6 research” means—

7 (A) patient-oriented clinical research con-
8 ducted with human subjects;

9 (B) research on the causes and con-
10 sequences of disease in human populations in-
11 volving material of human origin (such as tissue
12 specimens and cognitive phenomena) for which
13 an investigator or colleague directly interacts
14 with human subjects in an outpatient or inpa-
15 tient setting to clarify a problem in human
16 physiology, pathophysiology or disease;

17 (C) epidemiologic or behavioral studies;

18 (D) outcomes research;

19 (E) health services research; or

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

22 (2) DIRECTOR.—The term “Director” means
23 the Director of the National Institutes of Health.

24 (3) ELIGIBLE ACADEMIC HEALTH CENTER.—

25 The term “eligible academic health center” means

1 an academic institution and an affiliated teaching
2 hospital, a teaching hospital, an independent re-
3 search institute, or a consortium of research institu-
4 tions which conduct clinical research and receive
5 funds from the Department of Health and Human
6 Services for basic, applied, or clinical biomedical or
7 behavioral research in the fields of dentistry, medi-
8 cine, or nursing.

9 (4) SECRETARY.—The term “Secretary” means
10 the Secretary of Health and Human Services.

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

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

17 (b) PURPOSES.—A grant under this section to an eli-
18 gible academic health center shall be used only for the fol-
19 lowing purposes:

20 (1) To establish career development programs
21 for new and mid-level clinician-investigators who are
22 fully committed to academic clinical research ca-
23 reers.

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

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

7 (c) CAREER DEVELOPMENT PROGRAMS.—

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

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

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

17 (C) other medical personnel who are crit-
18 ical to the conduct of clinical research activities.

19 (2) SALARY CAP.—Notwithstanding paragraph
20 (1), no funds under this section may be used to in-
21 crease the rate of pay of an individual to a rate
22 greater than the rate of basic pay for level I of the
23 Executive Schedule.

24 (d) ALLOCATION.—Of the amount appropriated to
25 carry out this section for a fiscal year, the Director shall

1 allocate such appropriated amount among the eligible aca-
2 demic health centers receiving a grant under this section
3 in an amount that bears the same relation to such appro-
4 priated amount as the investment in clinical research of
5 the grantee involved bears to the total investment in clin-
6 ical research of all eligible grantees under this section.

7 (e) APPLICATIONS.—To seek a grant under this sec-
8 tion, an eligible academic health center shall submit an
9 application to the Director in such manner, at such time,
10 and containing such information and assurances as the
11 Director may require.

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

16 (g) AUTHORIZATION OF APPROPRIATIONS.—To carry
17 out this section, there is authorized to be appropriated
18 \$40,000,000 for each of the fiscal years 2006 through
19 2010.

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

21 (a) AUTHORIZATION.—The Director shall make clin-
22 ical research infrastructure grants on a competitive basis
23 to eligible academic health centers.

24 (b) USE OF FUNDS.—The Director may not make a
25 grant to an eligible academic health center under this sec-

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

3 (1) Fostering the use of information technology
4 to facilitate the transformation of basic research
5 findings on disease mechanisms into the develop-
6 ment of new methodologies for diagnosis, therapy,
7 and prevention.

8 (2) To devise, deploy, and support new tech-
9 nologies that facilitate the clinical investigators' abil-
10 ity to—

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

13 (B) ensure the confidentiality of research
14 data; and

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

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

19 (A) a lack of up-to-date information tech-
20 nology systems;

21 (B) incompatible databases;

22 (C) a lack of connectivity between aca-
23 demic health centers, teaching hospitals, and
24 independent research institutes;

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

4 (E) the underrepresentation of some popu-
5 lations in clinical research.

6 (4) Sharing clinical research infrastructure
7 across academic health centers to enable and facili-
8 tate cross-center clinical research collaborations.

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

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

19 (e) AUTHORIZATION OF APPROPRIATIONS.—To carry
20 out this section, there is authorized to be appropriated
21 \$125,000,000 for each of fiscal years 2006 through 2010.

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

24 (a) GRANTS.—The Secretary may make grants to not
25 more than 5 eligible academic health centers to form part-

1 nerships between the center involved and health care pro-
2 viders for carrying out clinical human subject research for
3 the purpose of demonstrating how academic research cen-
4 ters may collaborate with the practicing health care com-
5 munity in such research.

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

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

14 (d) AUTHORIZATION OF APPROPRIATIONS.—To carry
15 out this section, there is authorized to be appropriated
16 \$25,000,000 for the period of fiscal years 2006 through
17 2010.

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