

108TH CONGRESS
2D SESSION

S. 2924

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.

IN THE SENATE OF THE UNITED STATES

OCTOBER 7, 2004

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

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.

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 2004”.

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) Without a sound infrastructure to accom-
12 plish this translation in a systematic and coherent
13 way, the sum of data and information produced by
14 the basic science enterprise will not result in tangible
15 public benefit.

16 (5) The clinical research environment is in-
17 creasingly encumbered by facility decay, incompat-
18 ible databases, shortage of qualified investigators,
19 rising costs, inadequate funding, and mounting un-
20 reimbursed regulatory burdens such as human sub-
21 ject research protections and additional record-keep-
22 ing requirements under the Health Insurance Port-
23 ability and Accountability Act of 1996.

24 **SEC. 3. DEFINITIONS.**

25 In this Act:

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

3 (2) ELIGIBLE ACADEMIC HEALTH CENTER.—
4 The term “eligible academic health center” means—

5 (A) an academic institution that receives
6 an annual average of not less than \$20,000,000
7 in grant funds from the Department of De-
8 fense, the Department of Veterans Affairs, and
9 the Department of Health and Human Services
10 for basic, applied, or clinical biomedical or be-
11 havioral research in the fields of dentistry, med-
12 icine, and nursing; or

13 (B) a consortium of such academic institu-
14 tions.

15 (3) SECRETARY.—The term “Secretary” means
16 the Secretary of Health and Human Services.

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

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

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

1 ter involved will use the grant only for the following pur-
2 poses:

3 (1) To defray the costs of unfunded Federal re-
4 quirements for the protection of human research
5 subjects, including the costs of complying with the
6 Health Insurance Portability and Accountability Act
7 of 1996 (Pub. Law 104–191) and maintaining insti-
8 tutional review boards.

9 (2) To support activities leading to innovative
10 ways to meet the requirements described in para-
11 graph (1) in an efficient and cost effective manner.

12 (c) ALLOCATION.—Of the amount appropriated to
13 carry out this section for a fiscal year, the Director shall
14 allocate such appropriated amount among the eligible aca-
15 demic health centers receiving a grant under this section
16 in an amount that bears the same relation to such appro-
17 priated amount as the investment in clinical research of
18 the grantee involved bears to the total investment in clin-
19 ical research of all grantees under this section.

20 (d) APPLICATIONS.—To be eligible for a grant under
21 this section, an eligible academic health center shall sub-
22 mit an application to the Director in such manner, at such
23 time, and containing such information and assurances as
24 the Director may require.

1 (e) AUTHORIZATION OF APPROPRIATIONS.—To carry
 2 out this section, there is authorized to be appropriated
 3 \$40,000,000 for each of the fiscal years 2005 through
 4 2009.

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

6 (a) AUTHORIZATION.—The Director may award clin-
 7 ical research infrastructure grants on a competitive basis
 8 to eligible academic health centers.

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

13 (1) Infrastructure that is necessary to facilitate
 14 the transfer of new understandings of disease mech-
 15 anisms gained in the laboratory into the develop-
 16 ment of new methodologies for diagnosis, therapy,
 17 and prevention.

18 (2) The initial testing of human subjects.

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

21 (A) a lack of up-to-date information tech-
 22 nology systems;

23 (B) incompatible databases;

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

4 (D) a shortage of willing participants.

5 (c) APPLICATIONS.—To be eligible for a grant under
6 this section, an eligible academic health center shall sub-
7 mit an application to the Director in such manner, at such
8 time, and containing such information and assurances as
9 the Director may require.

10 (d) AUTHORIZATION OF APPROPRIATIONS.—To carry
11 out this section, there is authorized to be appropriated
12 \$125,000,000 for each of fiscal years 2005 through 2009.

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

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

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

1 (c) AUTHORIZATION OF APPROPRIATIONS.—There is
2 authorized to be appropriated to carry out this section
3 \$25,000,000 for the period of fiscal years 2005 through
4 2009.

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