

109TH CONGRESS  
1ST SESSION

# H. R. 2308

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

MAY 11, 2005

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.

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) The term “clinical research” means—

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

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

16 (C) epidemiologic or behavioral studies;

17 (D) outcomes research;

18 (E) health services research; or

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

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

23 (3) The term “eligible academic health center”  
24 means an academic institution and an affiliated  
25 teaching hospital, a teaching hospital, an inde-

1       pendent research institute, or a consortium of re-  
2       search institutions which conduct clinical research  
3       and receive funds from the Department of Health  
4       and Human Services for basic, applied, or clinical  
5       biomedical or behavioral research in the fields of  
6       dentistry, medicine, and nursing.

7               (4) The term “Secretary” means the Secretary  
8       of Health and Human Services.

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

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

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

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

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

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

4       (c) CAREER DEVELOPMENT PROGRAMS.—

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

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

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

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

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

21       (d) ALLOCATION.—Of the amount appropriated to  
22 carry out this section for a fiscal year, the Director shall  
23 allocate such appropriated amount among the eligible aca-  
24 demic health centers receiving a grant under this section  
25 in an amount that bears the same relation to such appro-

1 priated amount as the investment in clinical research of  
2 the grantee involved bears to the total investment in clin-  
3 ical research of all eligible grantees under this section.

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

9 (f) 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 purposes described in subsection (b).

13 (g) AUTHORIZATION OF APPROPRIATIONS.—To carry  
14 out this section, there is authorized to be appropriated  
15 \$40,000,000 for each of the fiscal years 2006 through  
16 2010.

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

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

21 (b) USE OF FUNDS.—The Director may not make a  
22 grant to an eligible academic health center under this sec-  
23 tion unless the center agrees to use the grant only for the  
24 following:

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

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

8                   (A) a lack of up-to-date information tech-  
9                   nology systems;

10                   (B) incompatible databases;

11                   (C) a lack of connectivity between aca-  
12                   demic health centers, teaching hospitals, and  
13                   independent research institutes;

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

17                   (E) the underrepresentation of some popu-  
18                   lations in clinical research.

19           (3) Sharing clinical research infrastructure  
20           across academic health centers to enable and facili-  
21           tate cross-center clinical research collaborations.

22           (c) REPORTS.—The Director shall require each re-  
23           cipient of a grant under this section to submit an annual  
24           report to the Director detailing how the recipient has used

1 the grant to meet the objectives described in subsection  
2 (b).

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

8 (e) AUTHORIZATION OF APPROPRIATIONS.—To carry  
9 out this section, there is authorized to be appropriated  
10 \$125,000,000 for each of fiscal years 2006 through 2010.

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

13 (a) GRANTS.—The Secretary may make grants to not  
14 more than 5 eligible academic health centers to form part-  
15 nerships between the center involved and health care pro-  
16 viders for carrying out clinical human subject research for  
17 the purpose of demonstrating how academic research cen-  
18 ters may collaborate with the practicing health care com-  
19 munity in such research.

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

23 (c) APPLICATIONS.—To seek a grant under this sec-  
24 tion, an eligible academic health center shall submit an  
25 application to the Director in such manner, at such time,



1 and containing such information and assurances as the  
2 Director may require.

3 (d) AUTHORIZATION OF APPROPRIATIONS.—To carry  
4 out this section, there is authorized to be appropriated  
5 \$25,000,000 for the period of fiscal years 2006 through  
6 2010.

