

112<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# S. 1840

To amend the Public Health Service Act to expand and intensify programs of the National Institutes of Health with respect to translational research and related activities concerning Down syndrome, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

NOVEMBER 10, 2011

Mr. BROWN of Ohio (for himself and Ms. COLLINS) 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 amend the Public Health Service Act to expand and intensify programs of the National Institutes of Health with respect to translational research and related activities concerning Down syndrome, 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 “Trisomy 21 Research  
5       Centers of Excellence Act of 2011”.

1 **SEC. 2. NIH DOWN SYNDROME RESEARCH ACTIVITIES.**

2 Part B of title IV of the Public Health Service Act  
3 (42 U.S.C. 284 et seq.) is amended by adding at the end  
4 of the title the following:

5 **“SEC. 409K. DOWN SYNDROME RESEARCH ACTIVITIES.**

6 “(a) EXPANSION, INTENSIFICATION, AND COORDINA-  
7 TION OF ACTIVITIES.—

8 “(1) IN GENERAL.—The Director of NIH, act-  
9 ing through the Director of the Eunice Kennedy  
10 Shriver National Institute of Child Health and  
11 Human Development, shall expand and intensify  
12 programs of the National Institutes of Health with  
13 respect to research and related activities concerning  
14 Down syndrome. The Director of NIH shall carry  
15 out such programs in coordination with a working  
16 group composed of representatives of the relevant in-  
17 stitutes, centers, offices, and agencies of the Na-  
18 tional Institutes of Health.

19 “(2) NIH RESEARCH PLAN ON DOWN SYN-  
20 DROME.—The Director of NIH shall publish a re-  
21 search plan on Down syndrome, and update it every  
22 5 years or as appropriate.

23 “(b) CENTERS OF EXCELLENCE.—

24 “(1) IN GENERAL.—In carrying out subsection  
25 (a)(1), the Director of NIH shall award grants and  
26 contracts to public or nonprofit private entities to

1 pay all or part of the cost of planning, establishing,  
2 improving, and providing basic operating support for  
3 centers of excellence regarding translational research  
4 on Down syndrome. To the extent and in the  
5 amount of appropriations made in advance, the Di-  
6 rector of NIH shall provide for the establishment of  
7 at least 6 such centers of excellence.

8 “(2) BASIC, TRANSLATIONAL, AND CLINICAL  
9 RESEARCH.—Each center receiving funds under  
10 paragraph (1) shall contribute to a comprehensive  
11 research portfolio for Down syndrome building upon  
12 the recommendations set forth in the NIH Research  
13 Plan on Down Syndrome published on October 8,  
14 2007, have a primary focus on Down syndrome, pro-  
15 vide an optimal venue and infrastructure for patient-  
16 oriented research, and conduct basic, clinical, and  
17 translational research on Down syndrome, including  
18 research on one or more of the following:

19 “(A) Early detection, diagnosis, and treat-  
20 ment of Down syndrome.

21 “(B) The biological mechanisms respon-  
22 sible for structural and functional anomalies in  
23 cells and tissues affected by Down syndrome.

1           “(C) The biological mechanisms respon-  
2           sible for cognitive and behavioral dysfunction  
3           resulting from Down syndrome.

4           “(D) Novel biomedical and pharma-  
5           cological interventions designed to promote or  
6           enhance cognition and related brain functions  
7           and activities of daily living (ADLs).

8           “(E) Co-occurrence of and treatments for  
9           associated medical and neurobehavioral dis-  
10          orders.

11          “(F) Developmental disorders, interven-  
12          tions for congenital heart disease, obstructive  
13          sleep apnea, coronary heart disease, obesity,  
14          and metabolism.

15          “(G) Contributions of genetic variation to  
16          clinical presentation as targets for therapy.

17          “(H) Identification of biomarkers for com-  
18          plex phenotypes.

19          “(I) Noninvasive imaging in support of ef-  
20          forts regarding other genotype and phenotypes  
21          of Down syndrome.

22          “(J) Pharmacological and other therapies  
23          for common features of Down syndrome includ-  
24          ing Alzheimer’s disease and other Down syn-  
25          drome-related disorders.

1           “(K) Research related to improving the  
2 quality of life for individuals with Down syn-  
3 drome and their families.

4           “(L) Research training programs aimed at  
5 increasing the numbers of scientists who are  
6 trained to carry out these research directions.

7           “(3) SERVICES FOR PATIENTS.—

8           “(A) IN GENERAL.—A center receiving  
9 funds under paragraph (1) shall expend  
10 amounts provided under such paragraph to  
11 carry out a program to make individuals aware  
12 of opportunities to participate as subjects in re-  
13 search conducted by the centers receiving funds  
14 under such paragraph.

15           “(B) REFERRALS AND COSTS.—A program  
16 under subparagraph (A) shall, in accordance  
17 with such criteria as the Director of NIH may  
18 establish, provide to the subjects described in  
19 such subparagraph referrals for health and  
20 other services and such patient care costs as  
21 are required for research.

22           “(C) AVAILABILITY AND ACCESS.—In  
23 awarding grants under this section, the Direc-  
24 tor of NIH shall require the applicant to dem-  
25 onstrate, and shall take into consideration, the

1           availability of and access to health and medical  
2           services described in subparagraph (B).

3           “(4) TRAINING PROGRAM FOR CLINICIANS AND  
4           SCIENTISTS.—Each center receiving funds under  
5           paragraph (1) shall establish or expand training pro-  
6           grams for medical and allied health clinicians and  
7           scientists in research relevant to Down syndrome.

8           “(5) COORDINATION OF CENTERS; REPORTS.—  
9           The Director of NIH shall—

10           “(A) provide for the coordination of infor-  
11           mation sharing among the centers receiving  
12           funds under paragraph (1) and ensure regular  
13           communication among such centers; and

14           “(B) require the centers to submit periodic  
15           reports to the Director on their activities.

16           “(6) ORGANIZATION OF CENTERS.—Each cen-  
17           ter receiving funds under paragraph (1) shall use  
18           the facilities of a single institution meeting such re-  
19           quirements as may be prescribed by the Director of  
20           NIH, be formed from a virtual consortium or net-  
21           work of such institutions, or both.

22           “(7) DURATION OF SUPPORT.—

23           “(A) IN GENERAL.—Subject to subpara-  
24           graph (B), the Director of NIH may not pro-  
25           vide support to a center receiving funds under

1 paragraph (1) for a period of more than 5  
2 years.

3 “(B) EXTENSION.—The period referred to  
4 in subparagraph (A) may be extended for 1 or  
5 more additional periods not exceeding 5 years  
6 if—

7 “(i) the operations of the center have  
8 been reviewed by an appropriate technical  
9 and scientific peer review group established  
10 by the Director of NIH; and

11 “(ii) such group has recommended to  
12 the Director that such period be extended.

13 “(c) DOWN SYNDROME CONSORTIUM.—In carrying  
14 out subsection (a)(1), the Director of NIH may establish  
15 a Down Syndrome Consortium to facilitate the exchange  
16 of information and to make the research effort on Down  
17 syndrome more efficient and effective by assuring con-  
18 sistent communication, minimizing duplication of effort,  
19 and integrating the varied perspectives of partner agen-  
20 cies, organizations, and individuals.

21 “(d) REPORT TO CONGRESS.—Not later than Janu-  
22 ary 1, 2012, and each January 1 thereafter, the Secretary  
23 of Health and Human Services shall prepare and submit  
24 to the appropriate committees of the Congress a report  
25 concerning the implementation of this section.

1       “(e) AUTHORIZATION OF APPROPRIATIONS.—To  
2 carry out this section, there are authorized to be appro-  
3 priated \$6,000,000 for each of fiscal years 2012 through  
4 2017.”.

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