

112TH CONGRESS
1ST SESSION

H. R. 2695

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.

IN THE HOUSE OF REPRESENTATIVES

JULY 29, 2011

Mrs. MCMORRIS RODGERS (for herself, Mr. VAN HOLLEN, and Mr. SESSIONS) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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