

119TH CONGRESS
1ST SESSION

H. R. 3491

To amend the Public Health Service Act to authorize the Secretary of Health and Human Services to carry out a program of research, training, and investigation related to Down syndrome, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2025

Ms. DEGETTE (for herself, Mr. HUDSON, Ms. DELAURO, Mr. COLE, Ms. NORTON, and Mr. STAUBER) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to authorize the Secretary of Health and Human Services to carry out a program of research, training, and investigation related to 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 “DeOndra Dixon IN-
5 CLUDE Project Act of 2025”.

1 **SEC. 2. DEONDRA DIXON INCLUDE PROJECT.**

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 the following:

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

6 “(a) IN GENERAL.—The Director of NIH shall carry
7 out a program of research, training, and investigation re-
8 lated to Down syndrome to be known as the ‘INvestigation
9 of Co-occurring conditions across the Lifespan to Under-
10 stand Down syndromE Project’ or the ‘INCLUDE
11 Project’.

12 “(b) PROGRAM ELEMENTS.—The program under
13 subsection (a) shall include—

14 “(1) high-risk, high-reward research on the ef-
15 fects of trisomy 21 on human development and
16 health;

17 “(2) promoting research for participants with
18 Down syndrome across the lifespan, including cohort
19 studies to facilitate improved understanding of
20 Down syndrome and co-occurring conditions and de-
21 velopment of new interventions;

22 “(3) expanding the number of clinical trials
23 that are inclusive of, or expressly for, participants
24 with Down syndrome, including novel biomedical and
25 pharmacological interventions and other therapies

1 designed to promote or enhance activities of daily
2 living;

3 “(4) research on the biological mechanisms in
4 individuals with Down syndrome pertaining to struc-
5 tural, functional, and behavioral anomalies and dys-
6 function as well as stunted growth;

7 “(5) supporting research to improve diagnosis
8 and treatment of conditions co-occurring with Down
9 syndrome, including the identification of biomarkers
10 related to risk factors, diagnosis, and clinical re-
11 search and therapeutics;

12 “(6) research on the causes of increased preva-
13 lence, and concurrent treatment, of co-occurring con-
14 ditions, such as Alzheimer’s disease and related de-
15 mentias and autoimmunity, in individuals with Down
16 syndrome; and

17 “(7) research, training, and investigation on im-
18 proving the quality of life of individuals with Down
19 syndrome and their families.

20 “(c) COORDINATION; PRIORITIZING NONDUPLICA-
21 TIVE RESEARCH.—The Director of NIH shall ensure
22 that—

23 “(1) the programs and activities of the insti-
24 tutes and centers of the National Institutes of
25 Health relating to Down syndrome and co-occurring

1 conditions are coordinated, including through the
2 Office of the Director of NIH and priority-setting
3 reviews conducted pursuant to section 402(b)(3);
4 and

5 “(2) such institutes and centers, prioritize, as
6 appropriate, Down syndrome research that does not
7 duplicate existing research activities of the National
8 Institutes of Health.

9 “(d) CONSULTATION WITH STAKEHOLDERS.—In
10 carrying out activities under this section, the Director of
11 NIH shall, as appropriate and to the maximum extent fea-
12 sible, consult with relevant stakeholders, including patient
13 advocates, to ensure that such activities take into consid-
14 eration the needs of individuals with Down syndrome.

15 “(e) BIENNIAL REPORTS TO CONGRESS.—

16 “(1) IN GENERAL.—The Director of NIH shall
17 submit, on a biennial basis, to the Committee on
18 Energy and Commerce and the Subcommittee on
19 Labor, Health and Human Services, Education, and
20 Related Agencies of the Committee on Appropria-
21 tions of the House of Representatives and the Com-
22 mittee on Health, Education, Labor, and Pensions
23 and the Subcommittee on Labor, Health and
24 Human Services, Education, and Related Agencies
25 of the Committee on Appropriations of the Senate,

1 a report that catalogs the research conducted or
2 supported under this section.

3 “(2) CONTENTS.—Each report under para-
4 graph (1) shall include—

5 “(A) identification of the institute or cen-
6 ter involved;

7 “(B) a statement of whether the research
8 is or was being carried out directly by such in-
9 stitute or center or by multiple institutes and
10 centers; and

11 “(C) identification of any resulting real-
12 world evidence that is or may be used for clin-
13 ical research and medical care for patients with
14 Down syndrome.”.

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