

Union Calendar No.

119TH CONGRESS
2^D SESSION

H. R. 3491

[Report No. 119-]

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

JUNE --, 2026

Committed to the Committee of the Whole House on the State of the Union,
and ordered to be printed

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”.

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

7 Part B of title IV of the Public Health Service Act
8 (42 U.S.C. 284 et seq.) is amended by adding at the end
9 the following:

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

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

17 “(b) PROGRAM ELEMENTS.—The program under
18 subsection (a) shall include—

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

22 “(2) promoting research for participants with
23 Down syndrome across the lifespan, including cohort
24 studies to facilitate improved understanding of

1 Down syndrome and co-occurring conditions and de-
2 velopment of new interventions;

3 “(3) expanding the number of clinical trials
4 that are inclusive of, or expressly for, participants
5 with Down syndrome, including novel biomedical and
6 pharmacological interventions and other therapies
7 designed to promote or enhance activities of daily
8 living;

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

13 “(5) supporting research to improve diagnosis
14 and treatment of conditions co-occurring with Down
15 syndrome, including the identification of biomarkers
16 related to risk factors, diagnosis, and clinical re-
17 search and therapeutics;

18 “(6) research on the causes of increased preva-
19 lence, and concurrent treatment, of co-occurring con-
20 ditions, such as Alzheimer’s disease and related de-
21 mentias and autoimmunity, in individuals with Down
22 syndrome; and

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

1 “(c) COORDINATION; PRIORITIZING NONDUPLICA-
2 TIVE RESEARCH.—The Director of NIH shall ensure
3 that—

4 “(1) the programs and activities of the insti-
5 tutes and centers of the National Institutes of
6 Health relating to Down syndrome and co-occurring
7 conditions are coordinated, including through the
8 Office of the Director of NIH and priority-setting
9 reviews conducted pursuant to section 402(b)(3);
10 and

11 “(2) such institutes and centers, prioritize, as
12 appropriate, Down syndrome research that does not
13 duplicate existing research activities of the National
14 Institutes of Health.

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

21 “(e) BIENNIAL REPORTS TO CONGRESS.—

22 “(1) IN GENERAL.—The Director of NIH shall
23 submit, on a biennial basis, to the Committee on
24 Energy and Commerce and the Subcommittee on
25 Labor, Health and Human Services, Education, and

1 Related Agencies of the Committee on Appropria-
2 tions of the House of Representatives and the Com-
3 mittee on Health, Education, Labor, and Pensions
4 and the Subcommittee on Labor, Health and
5 Human Services, Education, and Related Agencies
6 of the Committee on Appropriations of the Senate,
7 a report that catalogs the research conducted or
8 supported under this section.

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

11 “(A) identification of the institute or cen-
12 ter involved;

13 “(B) a statement of whether the research
14 is or was being carried out directly by such in-
15 stitute or center or by multiple institutes and
16 centers; and

17 “(C) identification of any resulting real-
18 world evidence that is or may be used for clin-
19 ical research and medical care for patients with
20 Down syndrome.”.