

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 7406
OFFERED BY M. _____**

Strike all after the enacting clause and insert the following:

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “DeOndra Dixon IN-
3 CLUDE Project Act of 2024”.

4 **SEC. 2. DOWN SYNDROME RESEARCH.**

5 Part A of title IV of the Public Health Service Act
6 (42 U.S.C. 281 et seq.) is amended by adding at the end
7 the following:

8 **“SEC. 404P. DOWN SYNDROM RESEARCH.**

9 “(a) IN GENERAL.—The Secretary, acting through
10 the Office of the Director of NIH, and in consultation with
11 other Federal agencies and partners, shall carry out a pro-
12 gram of research, training, and investigation related to
13 Down syndrome to be known as the ‘INvestigation of Co-
14 occurring conditions across the Lifespan to Understand
15 Down syndromE Project’ or the ‘INCLUDE Project’.

16 “(b) PROGRAM ELEMENTS.—The program under
17 subsection (a) shall include research, training, and inves-
18 tigation related to—

1 “(1) high-risk, high reward basic science studies
2 of the effects of chromosome 21 on human develop-
3 ment and health;

4 “(2) assembling and maintaining a large study
5 population of individuals with Down syndrome;

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

12 “(4) the biological mechanisms in individuals
13 with Down syndrome responsible for structural and
14 functional anomalies in cells, tissues, and organs,
15 cognitive and behavioral dysfunction, and stunted
16 growth;

17 “(5) the identification of biomarkers for the de-
18 tection of risk factors, diagnosis, and customized
19 interventions and treatments for conditions co-occur-
20 ring with Down syndrome;

21 “(6) why several co-occurring conditions, such
22 as Alzheimer’s Disease and autoimmunity, are prev-
23 alent in individuals with Down syndrome and how
24 such conditions can be treated concurrently with
25 Down syndrome; and

1 “(7) improving the quality of life of individuals
2 with Down syndrome and their families.

3 “(c) COORDINATION; PRIORITIZING NONDUPLICA-
4 TIVE RESEARCH.—The Secretary shall ensure that—

5 “(1) the programs and activities of the insti-
6 tutes, centers, agencies, and offices of the National
7 Institutes of Health relating to Down Syndrome and
8 co-occurring conditions are coordinated, including
9 through the Division of Program Coordination,
10 Planning, and Strategic Initiatives under sections
11 402(b)(7) and 402A(c); and

12 “(2) such institutes, centers, agencies, and of-
13 fices prioritize, as appropriate, Down syndrome re-
14 search that does not duplicate existing research ac-
15 tivities of the National Institutes of Health.

16 “(d) TECHNICAL ASSISTANCE.—The Secretary shall
17 provide technical assistance to grantees and other involved
18 entities, as appropriate, for carrying out activities pursu-
19 ant to this section.

20 “(e) BIENNIAL REPORTS TO CONGRESS.—

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

1 and the Committee on Health, Education, Labor,
2 and Pensions and the Subcommittee on Labor,
3 Health and Human Services, Education, and Re-
4 lated Agencies of the Committee on Appropriations
5 of the Senate, a report that catalogs the research
6 conducted or supported under this section.

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

9 “(A) identification of the institute, center,
10 agency, office, or entity involved;

11 “(B) a statement of whether the research
12 is or was being carried out directly by the insti-
13 tute, center, agency, office, or entity or by mul-
14 tiple institutes, centers, agencies, offices, or en-
15 tities; and

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

20 “(f) AUTHORIZATION OF APPROPRIATIONS.—

21 “(1) IN GENERAL.—To carry out this section,
22 there is authorized to be appropriated \$250,000,000
23 for each of fiscal years 2025 through 2029.

24 “(2) SUPPLEMENT, NOT SUPPLANT.—Funds
25 appropriated to carry out this section shall be used

1 to supplement, not supplant, other funds allocated
2 by the National Institutes of Health for research
3 and other activities relating to Down syndrome.”.

