

111TH CONGRESS  
1ST SESSION

# S. 1762

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

---

## IN THE SENATE OF THE UNITED STATES

OCTOBER 7, 2009

Mr. BROWNBACK (for himself and Mr. BROWN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

## A BILL

To amend the Public Health Service Act to expand and intensify programs of the National Institutes of Health and the Centers for Disease Control and Prevention 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  
5       Translational Research Parity Act of 2009” or the “21  
6       Act”.

1 **SEC. 2. FINDINGS.**

2 The Congress makes the following findings:

3 (1) Down syndrome was named after John  
4 Langdon Down, the first physician to identify the  
5 syndrome.

6 (2) Down syndrome is the most frequent ge-  
7 netic cause of mild to moderate intellectual disabil-  
8 ities (mental retardation) and associated medical  
9 problems and occurs in one out of 733 live births,  
10 in all races and economic groups. Intellectual dis-  
11 ability is a disability characterized by significant lim-  
12 itations both in intellectual functioning and in  
13 adaptive behavior, which covers many everyday so-  
14 cial and practical skills. This disability originates be-  
15 fore the age of 18.

16 (3) Down syndrome is a chromosomal condition  
17 caused by an error in cell or chromosome division  
18 that usually results in the presence of an additional  
19 third chromosome 21 or “trisomy 21”. Three other  
20 forms of Down syndrome exist: translocation Down  
21 syndrome (where cells have two copies of chro-  
22 mosome 21 and a third hybrid copy of chromosome  
23 21 and another chromosome), mosaic Down syn-  
24 drome (where some but not all, cells have three cop-  
25 ies of chromosome 21), and segmental trisomy Down  
26 syndrome (where cells have an extra copy of a part

1 of chromosome 21 either added to an otherwise nor-  
2 mal 21 or as a hybrid copy of a part of chromosome  
3 21 and another chromosome).

4 (4) There are more than 400,000 people living  
5 with Down syndrome in the United States.

6 (5) Down syndrome incidence increases with the  
7 age of the mother, but due to higher fertility rates  
8 in younger women, the majority of children with  
9 Down syndrome are born to women under 35 years  
10 of age.

11 (6) Life expectancy for people with Down syn-  
12 drome has increased dramatically in recent decades,  
13 but varies significantly across various ethnic groups.  
14 People with Down syndrome attend school, work,  
15 participate in decisions that concern them, and con-  
16 tribute to society in many meaningful ways.

17 (7) The Children's Health Act of 2000 (Public  
18 Law 106–310) amended the Public Health Service  
19 Act (42 U.S.C. 201 et seq.) and included a number  
20 of provisions that addressed the research and sur-  
21 veillance needs of many disabilities such as autism,  
22 traumatic brain injury, Fragile X, juvenile diabetes,  
23 asthma, epilepsy, and others. However, this land-  
24 mark legislation did not address the significant re-  
25 search, surveillance, and clinical care needs of Down

1        syndrome and thus has been an impediment to  
 2        progress in the Down syndrome research community  
 3        over the last decade. This Act attempts to incor-  
 4        porate Down syndrome as an area of permissible re-  
 5        search and surveillance at the National Institutes of  
 6        Health and the Centers for Disease Control and  
 7        Prevention and will foster a better understanding of  
 8        Down syndrome.

9        **SEC. 3. NIH DOWN SYNDROME TRANSLATIONAL RESEARCH**  
 10        **AND SERVICE DEVELOPMENT ACTIVITIES.**

11        Part B of title IV of the Public Health Service Act  
 12        (42 U.S.C. 284 et seq.) is amended by adding at the end  
 13        the following:

14        **“SEC. 409J. DOWN SYNDROME TRANSLATIONAL RESEARCH**  
 15        **AND SERVICE DEVELOPMENT ACTIVITIES.**

16        “(a) EXPANSION, INTENSIFICATION, AND COORDINA-  
 17        TION OF ACTIVITIES.—

18                “(1) IN GENERAL.—The Director of NIH, in  
 19        coordination with the directors of the National Insti-  
 20        tute of Child Health and Human Development, the  
 21        National Heart, Lung, and Blood Institute, the Na-  
 22        tional Institute of Allergy and Infectious Diseases,  
 23        the National Institute of Neurological Disorders and  
 24        Stroke, the National Cancer Institute, the National  
 25        Institute on Aging, the National Institute of Mental

1 Health, and the other national research institutes as  
2 appropriate, shall expand and intensify programs of  
3 the National Institutes of Health with respect to  
4 translational research and related activities con-  
5 cerning Down syndrome.

6 “(2) COORDINATION.—The directors referred to  
7 in paragraph (1) shall jointly coordinate the pro-  
8 grams referred to in such paragraph and consult  
9 with the Down Syndrome Coordinating Committee  
10 established under subsection (d).

11 “(3) ALLOCATIONS BY DIRECTOR OF NIH.—The  
12 Director of NIH shall allocate the amounts appro-  
13 priated to carry out this section for each fiscal year  
14 among the national research institutes referred to in  
15 paragraph (1).

16 “(b) CENTERS OF EXCELLENCE.—

17 “(1) IN GENERAL.—The Director of NIH shall  
18 award grants and contracts under subsection (a)(1)  
19 to public or nonprofit private entities to pay all or  
20 part of the cost of planning, establishing, improving,  
21 and providing basic operating support for centers of  
22 excellence regarding translational research on Down  
23 syndrome. To the extent and in the amount of ap-  
24 propriations made in advance, the Director of NIH

1 shall provide for the establishment of at least 6 such  
2 centers of excellence.

3 “(2) TRANSLATIONAL RESEARCH.—Each center  
4 under paragraph (1) shall contribute to a com-  
5 prehensive research portfolio for Down syndrome  
6 building upon the recommendations set forth in the  
7 NIH Research Plan on Down Syndrome published in  
8 October 2007, have a primary focus on Down syn-  
9 drome, provide an optimal venue and infrastructure  
10 for patient-oriented research, and conduct basic,  
11 clinical, and translational research on Down syn-  
12 drome, including, but not limited to, research on the  
13 following:

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

16 “(B) The biological mechanisms respon-  
17 sible for structural and functional anomalies in  
18 cells and tissues affected by Down syndrome.

19 “(C) The biological mechanisms respon-  
20 sible for cognitive and behavioral dysfunction  
21 resulting from Down syndrome.

22 “(D) Novel biomedical and pharma-  
23 ceutical interventions designed to promote or  
24 enhance cognition and related brain functions  
25 and activities of daily living (ADLs).

1           “(E) Co-occurrence of and treatments for  
2 associated medical and neurobehavioral dis-  
3 orders.

4           “(F) Developmental disorders, interven-  
5 tions for congenital heart disease, obstructive  
6 sleep apnea, coronary heart disease, obesity,  
7 and metabolism.

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

10          “(H) Identification of biomarkers for com-  
11 plex phenotypes.

12          “(I) Accessibility of health care, evidence-  
13 based health practice research and support  
14 services, referral patterns, and complications.

15          “(J) Noninvasive imaging in support of ef-  
16 forts to other genotype and phenotypes of Down  
17 syndrome.

18          “(K) Pharmacological and other therapies  
19 for common features of Down syndrome includ-  
20 ing Alzheimer disease and other Down syn-  
21 drome related disorders.

22          “(3) SERVICES FOR PATIENTS.—

23           “(A) IN GENERAL.—A center under para-  
24 graph (1) shall expend amounts provided under  
25 such paragraph to carry out a program to make

1 individuals aware of opportunities to participate  
2 as subjects in research conducted by the cen-  
3 ters.

4 “(B) REFERRALS AND COSTS.—A program  
5 under subparagraph (A) shall, in accordance  
6 with such criteria as the Director may establish,  
7 provide to the subjects described in such sub-  
8 paragraph referrals for health and other serv-  
9 ices and such patient care costs as are required  
10 for research.

11 “(C) AVAILABILITY AND ACCESS.—In  
12 awarding grants under this section, the Direc-  
13 tor of NIH shall require the applicant to dem-  
14 onstrate, and shall take into consideration, the  
15 availability of and access to health and medical  
16 services described in subparagraph (B).

17 “(4) TRAINING PROGRAM FOR CLINICIAN AND  
18 SCIENTISTS.—Each center under paragraph (1) shall  
19 establish or expand training programs for medical  
20 and allied health clinicians and scientists in research  
21 relevant to Down syndrome.

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

24 “(A) provide for the coordination of infor-  
25 mation sharing among the centers under para-



1 graph (1) and ensure regular communication  
2 among such centers; and

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

5 “(6) ORGANIZATION OF CENTERS.—Each cen-  
6 ter under paragraph (1) shall use the facilities of a  
7 single institution meeting such requirements as may  
8 be prescribed by the Director of NIH, be formed  
9 from a consortium or network of such institutions,  
10 or both.

11 “(7) DURATION OF SUPPORT.—

12 “(A) IN GENERAL.—Subject to subpara-  
13 graph (B), the Director of NIH may not pro-  
14 vide support to a center established under para-  
15 graph (1) for a period of more than 5 years.

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

20 “(i) the operations of the center have  
21 been reviewed by an appropriate technical  
22 and scientific peer review group established  
23 by the Director of NIH; and

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

1       “(c) FACILITATION AND COORDINATION OF RE-  
 2 SEARCH.—The Director of NIH shall, in coordination of  
 3 the National Down Syndrome Patient Registry and  
 4 Biobank established under section 317U, provide for a  
 5 program under subsection (a)(1) under which samples of  
 6 tissues and genetic materials that are of use in research  
 7 on Down syndrome are donated, collected, preserved, and  
 8 made available for such research. The program shall—

9               “(1) be carried out in accordance with accepted  
 10 scientific and medical standards for the donation,  
 11 collection, and preservation of such samples; and

12               “(2) be linked with the National Down Syn-  
 13 drome Patient Registry and Biobank established  
 14 under section 317U to allow for systematic searches  
 15 of information.

16       “(d) COORDINATING COMMITTEE.—

17               “(1) IN GENERAL.—The Secretary shall estab-  
 18 lish the Down Syndrome Coordinating Committee  
 19 (referred to in this section as the ‘Coordinating  
 20 Committee’) to coordinate activities across the Na-  
 21 tional Institutes of Health and with other Federal  
 22 health programs and activities relating to Down syn-  
 23 drome.

1           “(2) COMPOSITION.—The Coordinating Com-  
2       mittee shall consist of not more than 15 members,  
3       of which—

4           “(A)  $\frac{2}{3}$  of such members shall represent  
5       governmental agencies, including—

6           “(i) the directors or their designees of  
7       each of the national research institutes in-  
8       volved in research with respect to Down  
9       syndrome;

10          “(ii) representatives of all other Fed-  
11       eral departments and agencies whose pro-  
12       grams involve health functions or respon-  
13       sibilities relevant to such diseases, includ-  
14       ing the Centers for Disease Control and  
15       Prevention, the Health Resources and  
16       Services Administration, and the Food and  
17       Drug Administration; and

18          “(iii) representatives of other govern-  
19       mental agencies that serve children and  
20       adults with Down syndrome, such as the  
21       Department of Education, the Department  
22       of Labor, and the Department of Housing  
23       and Urban Development; and

24          “(B)  $\frac{1}{3}$  of such members shall be public  
25       members, including a broad cross section of

1 persons with Down syndrome, parents or legal  
2 guardians of persons with Down syndrome, re-  
3 searchers, and clinicians.

4 “(3) APPOINTMENT; TERMS.—

5 “(A) IN GENERAL.—The Secretary, in con-  
6 sultation with Down syndrome stakeholder or-  
7 ganizations, shall appoint the members of the  
8 Coordinating Committee.

9 “(B) PUBLIC MEMBERS.—Members of the  
10 Coordinating Committee appointed under para-  
11 graph (2)(B) shall be appointed for a term of  
12 3 years, and may serve for an unlimited num-  
13 ber of terms if reappointed. At least two such  
14 public members shall be persons who are ac-  
15 tively engaged in research or clinical practice on  
16 Down syndrome. At least one such public mem-  
17 ber shall be a person with Down syndrome, and  
18 an additional, non-voting member, whose sole  
19 role shall be to support the member with Down  
20 syndrome, shall be identified with direct input  
21 from the member with Down syndrome.

22 “(4) CHAIR.—

23 “(A) DUTIES.—With respect to Down syn-  
24 drome, the Chair of the Coordinating Com-  
25 mittee shall—

1 “(i) serve as the principal advisor to  
 2 the Secretary, the Assistant Secretary for  
 3 Health, and the Director of NIH; and

4 “(ii) provide advice to the Director of  
 5 the Centers for Disease Control and Pre-  
 6 vention, the Commissioner of Food and  
 7 Drugs, and to the heads of other relevant  
 8 agencies.

9 “(B) APPOINTMENT; TERM.—The Chair of  
 10 the Coordinating Committee—

11 “(i) shall be selected by the Coordi-  
 12 nating Committee from among its mem-  
 13 bers; and

14 “(ii) shall be selected to serve a term  
 15 not to exceed 2 years.

16 “(5) ADMINISTRATIVE SUPPORT.—The Sec-  
 17 retary of Health and Human Services shall provide,  
 18 or arrange for an appropriate office or agency of the  
 19 Department of Health and Human Services to pro-  
 20 vide, necessary and appropriate administrative sup-  
 21 port to the Coordinating Committee.

22 “(6) MEETINGS.—The Coordinating Committee  
 23 shall meet as appropriate, as determined by the Sec-  
 24 retary in consultation with the Chair of the Coordi-  
 25 nating Committee.

1 “(e) PLAN FOR HHS ACTIVITIES.—

2 “(1) IN GENERAL.—Not later than 1 year after  
3 the date of enactment of this section, the Coordi-  
4 nating Committee shall develop a plan for con-  
5 ducting and supporting research and education on  
6 Down syndrome through the national research insti-  
7 tutes and shall periodically review and revise the  
8 plan. The plan shall—

9 “(A) provide for a broad range of research  
10 and education activities relating to biomedical,  
11 epidemiological, public perception, psychosocial,  
12 and rehabilitative issues, including studies of  
13 the impact of such conditions in rural and un-  
14 derserved communities;

15 “(B) identify priorities among the pro-  
16 grams and activities of the National Institutes  
17 of Health regarding such conditions; and

18 “(C) reflect input from a broad range of  
19 scientists, patients, and advocacy groups.

20 “(2) CERTAIN ELEMENTS OF PLAN.—The plan  
21 under paragraph (1) shall, with respect to Down  
22 syndrome, provide for the following as appropriate:

23 “(A) Basic research concerning the eti-  
24 ology and genetic contributions to the potential

1 causes and consequences of the chromosomal  
2 disorder.

3 “(B) Basic and clinical research for the de-  
4 velopment and evaluation of new treatments, in-  
5 cluding new biological agents.

6 “(C) Specific programs for identifying po-  
7 tential therapeutic agents and moving them into  
8 clinical trials in a timely manner.

9 “(D) Research to determine the reasons  
10 underlying the incidence and prevalence of var-  
11 ious forms of Down syndrome.

12 “(E) Information and education programs  
13 for health care professionals and the public.

14 “(f) REPORTS TO CONGRESS.—The Coordinating  
15 Committee shall biennially submit to the Committee on  
16 Energy and Commerce of the House of Representatives  
17 and the Committee on Health, Education, Labor, and  
18 Pensions of the Senate a report that describes the re-  
19 search, education, and other activities on Down syndrome  
20 being conducted or supported through the Department of  
21 Health and Human Services. Each such report shall in-  
22 clude the following:

23 “(1) The plan under subsection (e)(1) (or revi-  
24 sions to the plan, as the case may be).

1           “(2) Provisions specifying the amounts ex-  
2           pended by the Department of Health and Human  
3           Services with respect to Down syndrome.

4           “(3) Provisions identifying particular projects  
5           or types of projects that should in the future be con-  
6           sidered by the national research institutes or other  
7           entities in the field of research on Down syndrome.

8           “(g) PUBLIC INPUT.—The Secretary shall, under  
9           subsection (a)(1), provide for a means through which the  
10          public can obtain information on the existing and planned  
11          programs and activities of the Department of Health and  
12          Human Services with respect to Down syndrome and  
13          through which the Secretary can receive comments from  
14          the public regarding such programs and activities.

15          “(h) DEFINITION.—The term ‘translational research’  
16          means rigorous, evidence-based basic or clinical research  
17          with an emphasis on accelerating the development and de-  
18          livery of effective new therapies to patients.

19          “(i) AUTHORIZATION OF APPROPRIATIONS.—For the  
20          purpose of carrying out this section, there are authorized  
21          to be appropriated such sums as may be necessary for  
22          each of fiscal years 2011 through 2015. The authorization  
23          of appropriations established in the preceding sentence is  
24          in addition to any other authorization of appropriations  
25          that is available for conducting or supporting through the



1 National Institutes of Health research and other activities  
 2 with respect to Down syndrome.”.

3 **SEC. 4. CDC DOWN SYNDROME SURVEILLANCE AND RE-**  
 4 **SEARCH PROGRAMS.**

5 Part B of title III of the Public Health Service Act  
 6 (42 U.S.C. 243 et seq.) is amended by inserting after sec-  
 7 tion 317T the following:

8 **“SEC. 317U. DOWN SYNDROME SURVEILLANCE AND RE-**  
 9 **SEARCH PROGRAMS.**

10 “(a) IN GENERAL.—The Secretary, acting through  
 11 the Director of the Centers for Disease Control and Pre-  
 12 vention, may award grants and cooperative agreements to  
 13 public or nonprofit private entities (including State health  
 14 departments, political subdivisions of States, universities,  
 15 and other educational entities) for the collection, analysis,  
 16 and reporting of data on Down syndrome. In making such  
 17 awards, the Secretary may provide direct technical assist-  
 18 ance, including personnel support, in lieu of cash.

19 “(b) NATIONAL DOWN SYNDROME EPIDEMIOLOGY  
 20 PROGRAM.—

21 “(1) GRANTS.—The Secretary, acting through  
 22 the Director of the Centers for Disease Control and  
 23 Prevention, may award grants to public or nonprofit  
 24 private entities (including State health departments,  
 25 political subdivisions of States, universities, and

1 other educational entities) for the purpose of car-  
 2 rying out epidemiological activities regarding Down  
 3 syndrome, including collecting and analyzing infor-  
 4 mation on the number, incidence, correlates, and  
 5 symptoms of cases and the clinical utility (including  
 6 costs and benefits) of specific practice patterns. In  
 7 making such awards, the Secretary may provide di-  
 8 rect technical assistance, including personnel sup-  
 9 port, in lieu of cash.

10 “(2) NATIONAL SURVEILLANCE PROGRAM.—In  
 11 carrying out subsection (a), the Secretary shall—

12 “(A) provide for a national surveillance  
 13 program; and

14 “(B) where possible, ensure that the sur-  
 15 veillance program is coordinated with the data  
 16 and sample collection activities of the National  
 17 Down Syndrome Patient Registry and Biobank.

18 “(c) NATIONAL DOWN SYNDROME PATIENT REG-  
 19 ISTRY AND BIOBANK.—

20 “(1) IN GENERAL.—The Secretary, acting  
 21 through the Director of the Centers for Disease  
 22 Control and Prevention and in collaboration with an  
 23 eligible national organization and patient advocacy  
 24 organization, shall establish a National Down Syn-  
 25 drome Patient Registry and Biobank.

1           “(2) REQUIREMENTS.—The National Down  
2       Syndrome Patient Registry and Biobank—

3           “(A) shall be used, building upon the  
4       multi-disease bank of brain and other tissue of  
5       the National Institute of Child Health and  
6       Human Development—

7           “(i) to establish a centralized or dis-  
8       tributed brain, cell, tissue, DNA, and RNA  
9       bank;

10          “(ii) to well-characterize a cohort of  
11       patients for genotype-phenotype investiga-  
12       tions to inter-operate with the bank; and

13          “(iii) to correlate the nature and se-  
14       verity of cognitive deficits and age of onset  
15       and severity of dementia;

16          “(B) shall be used as a resource to prepare  
17       therapies and treatments for clinical trials of  
18       ongoing treatments for individuals with Down  
19       syndrome, including the encouragement to in-  
20       clude participants with Down syndrome in Na-  
21       tional Institutes of Health-funded clinical trials;  
22       and

23          “(C) shall include the collection and anal-  
24       ysis of longitudinal data related to individuals  
25       of all ages with Down syndrome, including in-

1           fants, young children, adolescents, and adults of  
2           all ages including older Americans.

3           “(d) CENTERS OF EXCELLENCE.—

4           “(1) COOPERATIVE AGREEMENTS.—In carrying  
5           out this section, the Secretary shall enter into coop-  
6           erative agreements with an eligible national organi-  
7           zation, a patient advocacy organization, and appro-  
8           priate academic health institutions to develop, imple-  
9           ment, and manage Down Syndrome Centers of Ex-  
10          cellence for the purpose of—

11                   “(A) providing clinical care for patients  
12                   with Down syndrome;

13                   “(B) coordinating research and clinical ac-  
14                   tivities with the activities of the National Down  
15                   Syndrome Registry and Biobank; and

16                   “(C) participating in a system for Down  
17                   syndrome patient data collection and analysis,  
18                   including the creation and use of a common  
19                   data entry and management system.

20           “(2) ELIGIBLE NATIONAL ORGANIZATION.—In  
21           this subsection, the term ‘eligible national organiza-  
22           tion’ means a national organization that—

23                   “(A) has expertise in the epidemiology of  
24                   Down syndrome; and

1           “(B) has the capacity to maintain a pa-  
2           tient registry or Biobank.

3           “(e) ADVISORY COMMITTEE.—

4           “(1) ESTABLISHMENT.—Not later than 90 days  
5           after the date of the enactment of this section, the  
6           Secretary, acting through the Director of the Cen-  
7           ters for Disease Control and Prevention, shall estab-  
8           lish a committee to be known as the Advisory Com-  
9           mittee on the National Down Syndrome Registry  
10          and Biobank (referred to in this section as the ‘Ad-  
11          visory Committee’).

12          “(2) MEMBERSHIP.—The Advisory Committee  
13          shall be composed of at least one member, to be ap-  
14          pointed by the Secretary, acting through the Direc-  
15          tor of the Centers for Disease Control and Preven-  
16          tion, representing each of the following:

17                 “(A) National voluntary health associa-  
18                 tions that focus solely on Down syndrome and  
19                 have demonstrated experience in Down syn-  
20                 drome research, care, and patient services.

21                 “(B) The National Institutes of Health, to  
22                 include, upon the recommendation of the Direc-  
23                 tor of the National Institutes of Health, rep-  
24                 resentatives from the Directors of the National  
25                 Institute of Child Health and Human Develop-

ment, National Heart, Lung, and Blood Institute, National Institute of Allergy and Infectious Diseases, National Institute of Neurological Disorders and Stroke, National Cancer Institute, National Institute on Aging, and National Institute of Mental Health.

“(C) The Agency for Toxic Substances and Disease Registry.

“(D) The Centers for Disease Control and Prevention.

“(E) Down Syndrome Centers of Excellence developed under subsection (d).

“(F) Individuals with Down syndrome and, for the sole purpose of supporting such individuals, their family members.

“(G) Clinicians with expertise on Down syndrome.

“(H) Epidemiologists with experience in data registries.

“(I) Geneticists or experts in genetics who have experience with the genetics of Down syndrome.

“(J) Statisticians.

“(K) Ethicists.

“(L) Attorneys.

1           “(M) Researchers with expertise on Down  
2           syndrome.

3           “(N) Research scientists with experience  
4           conducting translational research or creating  
5           systems that support translating basic discov-  
6           eries into treatments.

7           “(O) Experts in additional neurological  
8           diseases, as appropriate, based on development  
9           and implementation of national surveillance sys-  
10          tems for other neurological diseases and dis-  
11          orders.

12          “(P) Other individuals with an interest in  
13          developing and maintaining the National Down  
14          Syndrome Registry and Biobank.

15          For purposes of this paragraph, the Secretary may  
16          appoint a member to represent more than one cat-  
17          egory described in subparagraphs (A) through (P).

18          “(3) DUTIES.—The Advisory Committee shall  
19          review and make recommendations to the Secretary  
20          concerning—

21                 “(A) the establishment, operation, and  
22                 maintenance of the National Down Syndrome  
23                 Registry and Biobank;

24                 “(B) the type of information to be col-  
25                 lected and stored in the Registry and Biobank;

1           “(C) the manner in which such data is to  
2           be collected; and

3           “(D) the use and availability of such data  
4           including guidelines for such use.

5           “(4) ADMINISTRATIVE SUPPORT.—The Director  
6           of the Centers for Disease Control and Prevention  
7           shall provide administrative support that is nec-  
8           essary and appropriate, as determined by the Direc-  
9           tor, to the Advisory Committee.

10          “(5) MEETINGS.—The Advisory Committee  
11          shall meet as appropriate, as determined by the Di-  
12          rector of the Centers for Disease Control and Pre-  
13          vention.

14          “(6) REPORT.—Not later than 2 years after the  
15          date on which the Advisory Committee is estab-  
16          lished, the Advisory Committee shall submit a report  
17          concerning the review conducted under paragraph  
18          (3) that contains the recommendations of the Advi-  
19          sory Committee with respect to the results of such  
20          review.

21          “(f) COORDINATION WITH CENTERS OF EXCEL-  
22          LENCE.—The Secretary shall ensure that epidemiological  
23          and registry information under subsections (a), (b), (c),  
24          and (d) are made available to centers of excellence sup-  
25          ported under section 409C(b) by the Director of NIH.



1       “(g) DEFINITION.—The term ‘translational research’  
2 means rigorous, evidence-based basic or clinical research  
3 with an emphasis on accelerating the development and de-  
4 livery of effective new therapies to patients.

5       “(h) AUTHORIZATION OF APPROPRIATIONS.—To  
6 carry out this section, there are authorized to be appro-  
7 priated \$3,000,000 for fiscal year 2010 and \$500,000 for  
8 each of fiscal years 2011 through 2015.”.

9       **SEC. 5. REPORT TO CONGRESS.**

10       Not later than January 1, 2011, and each January  
11 1 thereafter, the Secretary of Health and Human Services  
12 shall prepare and submit to the appropriate committees  
13 of Congress a report concerning the implementation of  
14 this Act and the amendments made by this Act.

○