118TH CONGRESS
1st Session
HOUSE OF REPRESENTATIVES
REPORT
118–165

GABRIELLA MILLER KIDS FIRST RESEARCH ACT 2.0

AUGUST 25, 2023.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mrs. RODGERS of Washington, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 3391]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 3391) to extend the Gabriella Miller Kids First Pediatric Research Program at the National Institutes of Health, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Gabriella Miller Kids First Research Act 2.0".

SEC. 2. FUNDING FOR THE PEDIATRIC RESEARCH INITIATIVE.

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended—

(1) in section 402A(a)(2) (42 U.S.C. 282a(a)(2))—

(A) in the heading—

(i) by striking "10-YEAR"; and

(ii) by striking "THROUGH COMMON FUND";

(B) by striking "to the Common Fund" and inserting "to the Division of Program Coordination, Planning, and Strategic Initiatives";

(C) by striking "10-Year";

(D) by striking "and reserved under subsection (c)(1)(B)(i) of this section"; and

(E) by striking "2014 through 2023" and inserting "2024 through 2028";

(2) in each of paragraphs (1)(A) and (2)(C) of section 402A(c) (42 U.S.C. 282a(c)), by striking "section 402(b)(7)(B)" and inserting "section 402(b)(7)(B)(i)"; and

(3) in section 402(b)(7)(B)(ii) (42 U.S.C. 282(b)(7)(B)(ii)), by striking "the Common Fund" and inserting "the Division of Program Coordination, Planning, and Strategic Initiatives".

SEC. 3. COORDINATION OF NIH FUNDING FOR PEDIATRIC RESEARCH.

(a) SENSE OF CONGRESS.—It is the sense of the Congress that the Director of the National Institutes of Health should continue to oversee and coordinate research that is conducted or supported by the National Institutes of Health for research on pediatric cancer and other pediatric diseases and conditions, including through the Pediatric Research Initiative Fund.

(b) AVOIDING DUPLICATION.—Section 402(b)(7)(B)(ii) of the Public Health Service Act (42 U.S.C. 282(b)(7)(B)(ii)) is amended by inserting "and shall prioritize, as appropriate, such pediatric research that does not duplicate existing research activities of the National Institutes of Health" before "; and".

SEC. 4. REPORT ON PROGRESS AND INVESTMENTS IN PEDIATRIC RESEARCH.

Not later than 5 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report that—

(1) details pediatric research projects and initiatives receiving funds allocated pursuant to section 402(b)(7)(B)(ii) of the Public Health Service Act (42 U.S.C. 282(b)(7)(B)(ii)); and

(2) summarizes advancements made in pediatric research with funds allocated pursuant to such section.

PURPOSE AND SUMMARY

The bill reauthorizes funding for the National Institute of Health's (NIH) Gabriella Miller Kids First Pediatric Research Program. The bill also requires coordinating federal efforts related to pediatric cancer research, as well as a report detailing current federally funded programs and initiatives, and the advancements made.

BACKGROUND AND NEED FOR LEGISLATION

The Gabriella Miller Kids First Pediatric Research Program (Kids First) was created to facilitate additional research and education around the relationship between childhood cancer and structural birth defects, and the shared genetic pathways between these disorders. It is estimated that over 9,910 children in the United States under the age of 15 will be diagnosed with cancer in 2023.[1] At the same time, one in 33 infants born in the United States has a birth defect. Birth defects are the leading cause of death during the first year of life, and account for half of all pediatric hos-

[1] Key Statistics for Childhood Cancers, American Cancer Society, https://www.cancer.org/cancer/types/cancer-in children/key-statistics.html.

pitalizations.[2] Research has shown that children with birth defects have an increased risk of developing childhood cancer. This suggests there are shared genetic pathways underlying some types of childhood cancer and structural birth defects, though more coordinated research and a better understanding of the role of genetics is needed.

COMMITTEE ACTION

On June 14, 2023, the Subcommittee on Health held a hearing on H.R. 3391. The Subcommittee received testimony from:

- Dr. Elizabeth Cherot, MD, MBA, Senior Vice President and Chief Medical Health Officer, March of Dimes;
- Dr. Alexis A. Thompson, MD, MPH, Chief of Division of Hematology, Elias Schwartz MD Endowed Chair in Hematology, Children's Hospital of Philadelphia, Professor of Pediatrics, University of Pennsylvania Perelman School of Medicine;
- Dr. Meredithe McNamara, MD, MS, FAAP, Assistant Professor, Yale School of Medicine;
- Dr. Miriam Grossman, MD, Child, Adolescent, and Adult Psychiatrist;
- Mr. George Manahan, Parkinson's Advocate and Patient; and,
- Mr. Kevin O'Connor, Assistant to the General President for Government Affairs and Political Action, International Association of Fire Fighters.

On, July 13, 2023, the Subcommittee on Health met in open markup session and forwarded H.R. 3391, as amended, to the full Committee by a record vote of 27 yeas and 0 nays. On July 19, 2023, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 3391, as amended, favorably reported to the House by a record vote of 50 yeas and 0 nays.

COMMITTEE VOTES

Clause 3(b) of rule XIII requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The following reflects the record votes taken during the Committee consideration:

[2] Overview, Gabriella Miller Kids First Pediatric Research Program (Kids First), NIH, https://commonfund.nih.gov/kidsfirst/overview.

COMMITTEE ON ENERGY AND COMMERCE
118TH CONGRESS
ROLL CALL VOTE # 7

BILL: H.R. 3391, the Gabriella Miller Kids First Research Act 2.0

AMENDMENT: A motion by Mrs. Rodgers to order H.R. 3391 favorably reported to the House, as amended (Final Passage).

DISPOSITION: **AGREED TO,** by a roll call vote of 50 yeas to 0 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Rep. Rodgers	X			Rep. Pallone	X		
Rep. Burgess	X			Rep. Eshoo	X		
Rep. Latta	X			Rep. DeGette	X		
Rep. Guthrie	X			Rep. Schakowsky	X		
Rep. Griffith	X			Rep. Matsui	X		
Rep. Bilirakis	X			Rep. Castor	X		
Rep. Johnson	X			Rep. Sarbanes	X		
Rep. Bucshon	X			Rep. Tonko	X		
Rep. Hudson	X			Rep. Clarke	X		
Rep. Walberg	X			Rep. Cárdenas	X		
Rep. Carter	X			Rep. Ruiz	X		
Rep. Duncan	X			Rep. Peters	X		
Rep. Palmer	X			Rep. Dingell	X		
Rep. Dunn	X			Rep. Veasey	X		
Rep. Curtis				Rep. Kuster	X		
Rep. Lesko	X			Rep. Kelly	X		
Rep. Pence	X			Rep. Barragán	X		
Rep. Crenshaw	X			Rep. Blunt Rochester	X		
Rep. Joyce	X			Rep. Soto	X		
Rep. Armstrong				Rep. Craig	X		
Rep. Weber	X			Rep. Schrier	X		
Rep. Allen	X			Rep. Trahan	X		
Rep. Balderson	X			Rep. Fletcher	X		
Rep. Fulcher	X						
Rep. Pfluger	X						
Rep. Harshbarger	X						
Rep. Miller-Meeks	X						
Rep. Cammack	X						
Rep. Obernolte	X						

07/19/2023

OVERSIGHT FINDINGS AND RECOMMENDATIONS

Pursuant to clause 2(b)(1) of rule X and clause 3(c)(1) of rule XIII, the Committee held a hearing and made findings that are reflected in this report.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to clause 3(c)(2) of rule XIII, the Committee finds that H.R. 3391 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII, at the time this report was filed, the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not available.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to facilitate research and education around the relationship between childhood cancer and structural birth defects by reauthorizing funding for the National Institute of Health's Gabriella Miller Kids First Pediatric Research Program and coordinating federal efforts related to pediatric cancer research.

DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 3391 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

RELATED COMMITTEE AND SUBCOMMITTEE HEARINGS

Pursuant to clause 3(c)(6) of rule XIII, the following related hearing was used to develop or consider H.R. 3391:

- On June 14, 2023, the Subcommittee on Health held a hearing on H.R. 3391. The Subcommittee received testimony from:
  - Dr. Elizabeth Cherot, MD, MBA, Senior Vice President and Chief Medical Health Officer, March of Dimes;
  - Dr. Alexis A. Thompson, MD, MPH, Chief of Division of Hematology, Elias Schwartz MD Endowed Chair in Hematology, Children's Hospital of Philadelphia, Professor of Pediatrics, University of Pennsylvania Perelman School of Medicine;

- Dr. Meredithe McNamara, MD, MS, FAAP, Assistant Professor, Yale School of Medicine;
- Dr. Miriam Grossman, MD, Child, Adolescent, and Adult Psychiatrist;
- Mr. George Manahan, Parkinsons Advocate and Patient; and,
- Mr. Kevin O'Connor, Assistant to the General President for Government Affairs and Political Action, International Association of Fire Fighters.

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974. At the time this report was filed, the estimate was not available.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 3391 contains no earmarks, limited tax benefits, or limited tariff benefits.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 provides a short title of "Gabriella Miller Kids First Research Act 2.0".

Section 2. Funding for the pediatric research initiative

Section 2 amends section 402 of the Public Health Service Act to extend funding for the Division of Program Coordination, Planning, and Strategic Initiatives for fiscal years 2024 through 2028.

Section 3. Coordination of NIH funding for pediatric research

Section 3 expresses the sense of Congress that the Director of the National Institutes of Health oversee and coordinate pediatric research supported by the NIH and amends section 402 of the Public Health Service Act to clarify pediatric research should not duplicate existing research activities of the NIH.

Section 4. Report on progress and investment in pediatric research

Section 4 directs the Secretary of Health and Human Services to submit a report no later than 5 years after the bill's enactment de-

tailing current federally funded pediatric research programs and initiatives and advancements made.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * * * *

TITLE IV—NATIONAL RESEARCH INSTITUTES

PART A—NATIONAL INSTITUTES OF HEALTH

* * * * * * *

APPOINTMENT AND AUTHORITY OF DIRECTOR OF NIH

SEC. 402. (a) The National Institutes of Health shall be headed by the Director of NIH who shall be appointed by the President by and with the advice and consent of the Senate. The Director of NIH shall perform functions as provided under subsection (b) and as the Secretary may otherwise prescribe.

(b) In carrying out the purposes of section 301, the Secretary, acting through the Director of NIH—

(1) shall carry out this title, including being responsible for the overall direction of the National Institutes of Health and for the establishment and implementation of general policies respecting the management and operation of programs and activities within the National Institutes of Health;

(2) shall coordinate and oversee the operation of the national research institutes, national centers, and administrative entities within the National Institutes of Health;

(3) shall, in consultation with the heads of the national research institutes and national centers, be responsible for program coordination across the national research institutes and national centers, including conducting priority-setting reviews, to ensure that the research portfolio of the National Institutes of Health is balanced and free of unnecessary duplication, and takes advantage of collaborative, cross-cutting research;

(4) shall assemble accurate data to be used to assess research priorities, including—

(A) information to better evaluate scientific opportunity, public health burdens, and progress in reducing health disparities; and

(B) data on study populations of clinical research, funded by or conducted at each national research institute and national center, which—

(i) specifies the inclusion of—

(I) women;

(II) members of minority groups;

(III) relevant age categories, including pediatric subgroups; and

(IV) other demographic variables as the Director of the National Institutes of Health determines appropriate;

(ii) is disaggregated by research area, condition, and disease categories; and

(iii) is to be made publicly available on the Internet website of the National Institutes of Health;

(5) shall ensure that scientifically based strategic planning is implemented in support of research priorities as determined by the agencies of the National Institutes of Health, and through the development, implementation, and updating of the strategic plan developed under subsection (m);

(6) shall ensure that the resources of the National Institutes of Health are sufficiently allocated for research projects identified in strategic plans;

(7)(A) shall, through the Division of Program Coordination, Planning, and Strategic Initiatives—

(i) identify research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis and would benefit from conducting or supporting additional research that involves collaboration between 2 or more national research institutes or national centers, or would otherwise benefit from strategic coordination and planning;

(ii) include information on such research in reports under section 403; and

(iii) in the case of such research supported with funds referred to in subparagraph (B)—

(I) require as appropriate that proposals include milestones and goals for the research;

(II) require that the proposals include timeframes for funding of the research; and

(III) ensure appropriate consideration of proposals for which the principal investigator is an individual who has not previously served as the principal investigator of research conducted or supported by the National Institutes of Health;

(B)(i) may, with respect to funds reserved under section 402A(c)(1) for the Common Fund, allocate such funds to the national research institutes and national centers for conducting and supporting research that is identified under subparagraph (A); and

(ii) shall, with respect to funds appropriated to ⟦the Common Fund⟧ *the Division of Program Coordination, Planning, and Strategic Initiatives* pursuant to section 402A(a)(2), allocate such funds to the national research institutes and national centers for making grants for pediatric research that is identified under subparagraph (A) *and shall prioritize, as appropriate, such pediatric research that does not duplicate existing research activities of the National Institutes of Health*; and

(C) may assign additional functions to the Division in support of responsibilities identified in subparagraph (A), as determined appropriate by the Director;

(8) shall, in coordination with the heads of the national research institutes and national centers, ensure that such institutes and centers—

(A) preserve an emphasis on investigator-initiated research project grants, including with respect to research involving collaboration between 2 or more such institutes or centers;

(B) when appropriate, maximize investigator-initiated research project grants in their annual research portfolios;

(C) foster collaboration between clinical research projects funded by the respective national research institutes and national centers that—

(i) conduct research involving human subjects; and

(ii) collect similar data; and

(D) encourage the collaboration described in subparagraph (C) to—

(i) allow for an increase in the number of subjects studied; and

(ii) utilize diverse study populations, with special consideration to biological, social, and other determinants of health that contribute to health disparities;

(9) shall ensure that research conducted or supported by the National Institutes of Health is subject to review in accordance with section 492 and that, after such review, the research is reviewed in accordance with section 492A(a)(2) by the appropriate advisory council under section 406 before the research proposals are approved for funding;

(10) shall have authority to review and approve the establishment of all centers of excellence recommended by the national research institutes;

(11)(A) shall oversee research training for all of the national research institutes and National Research Service Awards in accordance with section 487; and

(B) may conduct and support research training—

(i) for which fellowship support is not provided under section 487; and

(ii) that does not consist of residency training of physicians or other health professionals;

(12) may, from funds appropriated under section 402A(b), reserve funds to provide for research on matters that have not received significant funding relative to other matters, to respond to new issues and scientific emergencies, and to act on research opportunities of high priority;

(13) may, subject to appropriations Acts, collect and retain registration fees obtained from third parties to defray expenses for scientific, educational, and research-related conferences;

(14) for the national research institutes and administrative entities within the National Institutes of Health—

(A) may acquire, construct, improve, repair, operate, and maintain, at the site of such institutes and entities, laboratories, and other research facilities, other facilities, equipment, and other real or personal property, and

(B) may acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed ten years;

(15) may secure resources for research conducted by or through the National Institutes of Health;

(16) may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific peer review groups and scientific program advisory committees as are needed to carry out the requirements of this title and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups;

(17) may secure for the National Institutes of Health consultation services and advice of persons from the United States or abroad;

(18) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(19) may, for purposes of study, admit and treat at facilities of the National Institutes of Health individuals not otherwise eligible for such treatment;

(20) may accept voluntary and uncompensated services;

(21) may perform such other administrative functions as the Secretary determines are needed to effectively carry out this title;

(22) may appoint physicians, dentists, and other health care professionals, subject to the provisions of title 5, United States Code, relating to appointments and classifications in the competitive service, and may compensate such professionals subject to the provisions of chapter 74 of title 38, United States Code;

(23) shall designate a contact point or office to help innovators and physicians identify sources of funding available for pediatric medical device development;

(24) implement the Cures Acceleration Network described in section 480;

(25) may require recipients of National Institutes of Health awards to share scientific data, to the extent feasible, generated from such National Institutes of Health awards in a manner that is consistent with all applicable Federal laws and regulations, including such laws and regulations for the protection of—

(A) human research participants, including with respect to privacy, security, informed consent, and protected health information; and

(B) proprietary interests, confidential commercial information, and the intellectual property rights of the funding recipient;

(26) shall consult with the Assistant Secretary for Preparedness and Response, the Director of the Biomedical Advanced Research and Development Authority, the Director of the Centers for Disease Control and Prevention, and the heads of other Federal agencies and offices, as appropriate, regarding research needs to advance medical countermeasures to diagnose, mitigate, prevent, or treat harm from any biological agent or toxin, including emerging infectious diseases, chemical, radiological, or nuclear agent that may cause a public health emergency or other research needs related to emerging public health threats;

(27) shall consult with the Director of the Office of National Security within the Department of Health and Human Services, the Assistant Secretary for Preparedness and Response, the Director of National Intelligence, the Director of the Federal Bureau of Investigation, and the heads of other appropriate agencies on a regular basis, regarding biomedical research conducted or supported by the National Institutes of Health that may affect or be affected by matters of national security;

(28) shall ensure that recipients of awards from the National Institutes of Health, and, as appropriate and practicable, entities collaborating with such recipients, have in place and are adhering to appropriate technology practices and policies for the security of identifiable, sensitive information, including information collected, stored, managed, or analyzed by domestic and non-domestic entities; and

(29) shall ensure that recipients of awards from the National Institutes of Health are in compliance with the terms and conditions of such award, which may include activities to support awareness of, and compliance with, such terms and conditions by any subrecipients of the award.

Chapter 10 of title 5, United States Code, shall not apply to the duration of a peer review group appointed under paragraph (16). The members of such a group shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of such group. Not more than one-fourth of the members of any such group shall be officers or employees of the United States.

(c) The Director of NIH may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(d)(1) The Director of NIH may obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the period of service) the services of not more than 220 experts or consultants, with scientific or other professional qualifications, for the National Institutes of Health.

(2)(A) Except as provided in subparagraph (B), experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed, in accordance with title 5, United States Code, for their travel to and from their place of service and for other expenses associated with their assignment.

(B) Expenses specified in subparagraph (A) shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

(e) The Director of NIH shall—

(1) advise the agencies of the National Institutes of Health on medical applications of research;

(2) coordinate, review, and facilitate the systematic identification and evaluation of, clinically relevant information from research conducted by or through the national research institutes;

(3) promote the effective transfer of the information described in paragraph (2) to the health care community and to entities that require such information;

(4) monitor the effectiveness of the activities described in paragraph (3); and

(5) ensure that, after January 1, 1994, all new or revised health education and promotion materials developed or funded by the National Institutes of Health and intended for the general public are in a form that does not exceed a level of functional literacy, as defined in the National Literacy Act of 1991 (Public Law 102–73).

(f) There shall be in the National Institutes of Health an Associate Director for Prevention. The Director of NIH shall delegate to the Associate Director for Prevention the functions of the Director relating to the promotion of the disease prevention research programs of the national research institutes and the coordination of such programs among the national research institutes and between the national research institutes and other public and private entities, including elementary, secondary, and post-secondary schools. The Associate Director shall—

(1) annually review the efficacy of existing policies and techniques used by the national research institutes to disseminate the results of disease prevention and behavioral research programs; and

(2) recommend, coordinate, and oversee the modification or reconstruction of such policies and techniques to ensure maximum dissemination, using advanced technologies to the maximum extent practicable, of research results to such entities.

(h) The Secretary, acting through the Director of NIH and the Directors of the agencies of the National Institutes of Health, shall, in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research.

(i)(1)(A) The Secretary, acting through the Director of NIH, shall establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions (in this subsection referred to as the "data bank"). The activities of the data bank shall be integrated and coordinated with related activities of other agencies of the Department of Health and Human Services, and to the extent practicable, coordinated with other data banks containing similar information.

(B) The Secretary shall establish the data bank after consultation with the Commissioner of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health (including the National Library of Medicine), and the Director of the Centers for Disease Control and Prevention.

(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. The Secretary shall disseminate such information through information systems, which shall include toll-free telephone communications, available to individuals with serious or life-threatening diseases and conditions, to other members of the public, to health care providers, and to researchers.

(3) The data bank shall include the following:

(A) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions under regulations promulgated pursuant to section 505(i) of the Federal Food, Drug, and Cosmetic Act, which provides a description of the purpose of each experimental drug, either with the consent of the protocol sponsor, or when a trial to test effectiveness begins. Information provided shall consist of eligibility criteria for participation in the clinical trials, a description of the location of trial sites, and a point of contact for those wanting to enroll in the trial, and shall be in a form that can be readily understood by members of the public. Such information shall be forwarded to the data bank by the sponsor of the trial not later than 21 days after the approval of the protocol.

(B) Information pertaining to experimental treatments for serious or life-threatening diseases and conditions that may be available—

(i) under a treatment investigational new drug application that has been submitted to the Secretary under section 561(c) of the Federal Food, Drug, and Cosmetic Act; or

(ii) as a Group C cancer drug (as defined by the National Cancer Institute).

The data bank may also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatments.

(4) The data bank shall not include information relating to an investigation if the sponsor has provided a detailed certification to the Secretary that disclosure of such information would substantially interfere with the timely enrollment of subjects in the investigation, unless the Secretary, after the receipt of the certification, provides the sponsor with a detailed written determination that

such disclosure would not substantially interfere with such enrollment.

(5) Fees collected under section 736 of the Federal Food, Drug, and Cosmetic Act shall not be used in carrying out this subsection.

(j) EXPANDED CLINICAL TRIAL REGISTRY DATA BANK.—

(1) DEFINITIONS; REQUIREMENT.—

(A) DEFINITIONS.—In this subsection:

(i) APPLICABLE CLINICAL TRIAL.—The term "applicable clinical trial" means an applicable device clinical trial or an applicable drug clinical trial.

(ii) APPLICABLE DEVICE CLINICAL TRIAL.—The term "applicable device clinical trial" means—

(I) a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and

(II) a pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act.

(iii) APPLICABLE DRUG CLINICAL TRIAL.—

(I) IN GENERAL.—The term "applicable drug clinical trial" means a controlled clinical investigation, other than a phase I clinical investigation, of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act.

(II) CLINICAL INVESTIGATION.—For purposes of subclause (I), the term "clinical investigation" has the meaning given that term in section 312.3 of title 21, Code of Federal Regulations (or any successor regulation).

(III) PHASE I.—For purposes of subclause (I), the term "phase I" has the meaning given that term in section 312.21 of title 21, Code of Federal Regulations (or any successor regulation).

(iv) CLINICAL TRIAL INFORMATION.—The term "clinical trial information" means, with respect to an applicable clinical trial, those data elements that the responsible party is required to submit under paragraph (2) or under paragraph (3).

(v) COMPLETION DATE.—The term "completion date" means, with respect to an applicable clinical trial, the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated.

(vi) DEVICE.—The term "device" means a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act.

(vii) DRUG.—The term "drug" means a drug as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act or a biological product as defined in section 351 of this Act.

(viii) ONGOING.—The term "ongoing" means, with respect to a clinical trial of a drug or a device and to a date, that—

(I) 1 or more patients is enrolled in the clinical trial; and

(II) the date is before the completion date of the clinical trial.

(ix) RESPONSIBLE PARTY.—The term "responsible party", with respect to a clinical trial of a drug or device, means—

(I) the sponsor of the clinical trial (as defined in section 50.3 of title 21, Code of Federal Regulations (or any successor regulation)); or

(II) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under this subsection for the submission of clinical trial information.

(B) REQUIREMENT.—The Secretary shall develop a mechanism by which the responsible party for each applicable clinical trial shall submit the identity and contact information of such responsible party to the Secretary at the time of submission of clinical trial information under paragraph (2).

(2) EXPANSION OF CLINICAL TRIAL REGISTRY DATA BANK WITH RESPECT TO CLINICAL TRIAL INFORMATION.—

(A) IN GENERAL.—

(i) EXPANSION OF DATA BANK.—To enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials, the Secretary, acting through the Director of NIH, shall expand, in accordance with this subsection, the clinical trials registry of the data bank described under subsection (i)(1) (referred to in this subsection as the "registry data bank"). The Director of NIH shall ensure that the registry data bank is made publicly available through the Internet.

(ii) CONTENT.—The clinical trial information required to be submitted under this paragraph for an applicable clinical trial shall include—

(I) descriptive information, including—

(aa) a brief title, intended for the lay public;

(bb) a brief summary, intended for the lay public;

(cc) the primary purpose;

(dd) the study design;

(ee) for an applicable drug clinical trial, the study phase;

(ff) study type;

(gg) the primary disease or condition being studied, or the focus of the study;

(hh) the intervention name and intervention type;

(ii) the study start date;

(jj) the expected completion date;

(kk) the target number of subjects; and

(ll) outcomes, including primary and secondary outcome measures;

(II) recruitment information, including—

(aa) eligibility criteria;

(bb) gender;

(cc) age limits;

(dd) whether the trial accepts healthy volunteers;

(ee) overall recruitment status;

(ff) individual site status; and

(gg) in the case of an applicable drug clinical trial, if the drug is not approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act, specify whether or not there is expanded access to the drug under section 561 of the Federal Food, Drug, and Cosmetic Act for those who do not qualify for enrollment in the clinical trial and how to obtain information about such access;

(III) location and contact information, including—

(aa) the name of the sponsor;

(bb) the responsible party, by official title; and

(cc) the facility name and facility contact information (including the city, State, and zip code for each clinical trial location, or a toll-free number through which such location information may be accessed); and

(IV) administrative data (which the Secretary may make publicly available as necessary), including—

(aa) the unique protocol identification number;

(bb) other protocol identification numbers, if any; and

(cc) the Food and Drug Administration IND/IDE protocol number and the record verification date.

(iii) MODIFICATIONS.—The Secretary may by regulation modify the requirements for clinical trial information under this paragraph, if the Secretary provides a rationale for why such a modification improves and does not reduce such clinical trial information.

(B) FORMAT AND STRUCTURE.—

(i) SEARCHABLE CATEGORIES.—The Director of NIH shall ensure that the public may, in addition to keyword searching, search the entries in the registry data bank by 1 or more of the following criteria:

(I) The disease or condition being studied in the clinical trial, using Medical Subject Headers (MeSH) descriptors.

(II) The name of the intervention, including any drug or device being studied in the clinical trial.

(III) The location of the clinical trial.

(IV) The age group studied in the clinical trial, including pediatric subpopulations.

(V) The study phase of the clinical trial.

(VI) The sponsor of the clinical trial, which may be the National Institutes of Health or another Federal agency, a private industry source, or a university or other organization.

(VII) The recruitment status of the clinical trial.

(VIII) The National Clinical Trial number or other study identification for the clinical trial.

(ii) ADDITIONAL SEARCHABLE CATEGORY.—Not later than 18 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Director of NIH shall ensure that the public may search the entries of the registry data bank by the safety issue, if any, being studied in the clinical trial as a primary or secondary outcome.

(iii) OTHER ELEMENTS.—The Director of NIH shall also ensure that the public may search the entries of the registry data bank by such other elements as the Director deems necessary on an ongoing basis.

(iv) FORMAT.—The Director of the NIH shall ensure that the registry data bank is easily used by the public, and that entries are easily compared.

(C) DATA SUBMISSION.—The responsible party for an applicable clinical trial, including an applicable drug clinical trial for a serious or life-threatening disease or condition, that is initiated after, or is ongoing on the date that is 90 days after, the date of the enactment of the Food and Drug Administration Amendments Act of 2007, shall submit to the Director of NIH for inclusion in the registry data bank the clinical trial information described in of subparagraph (A)(ii) not later than the later of—

(i) 90 days after such date of enactment;

(ii) 21 days after the first patient is enrolled in such clinical trial; or

(iii) in the case of a clinical trial that is not for a serious or life-threatening disease or condition and that is ongoing on such date of enactment, 1 year after such date of enactment.

(D) POSTING OF DATA.—

(i) APPLICABLE DRUG CLINICAL TRIAL.—The Director of NIH shall ensure that clinical trial information for an applicable drug clinical trial submitted in accord-

ance with this paragraph is posted in the registry data bank not later than 30 days after such submission.

(ii) APPLICABLE DEVICE CLINICAL TRIAL.—The Director of NIH shall ensure that clinical trial information for an applicable device clinical trial submitted in accordance with this paragraph is posted publicly in the registry data bank—

(I) not earlier than the date of clearance under section 510(k) of the Federal Food, Drug, and Cosmetic Act, or approval under section 515 or 520(m) of such Act, as applicable, for a device that was not previously cleared or approved, and not later than 30 days after such date, unless the responsible party affirmatively requests that the Director of the National Institutes of Health publicly post such clinical trial information for an applicable device clinical trial prior to such date of clearance or approval; or

(II) for a device that was previously cleared or approved, not later than 30 days after the clinical trial information under paragraph (3)(C) is required to be posted by the Secretary.

(iii) OPTION TO MAKE CERTAIN CLINICAL TRIAL INFORMATION AVAILABLE EARLIER.—The Director of the National Institutes of Health shall inform responsible parties of the option to request that clinical trial information for an applicable device clinical trial be publicly posted prior to the date of clearance or approval, in accordance with clause (ii)(I).

(iv) COMBINATION PRODUCTS.—An applicable clinical trial for a product that is a combination of drug, device, or biological product shall be considered—

(I) an applicable drug clinical trial, if the Secretary determines under section 503(g) of the Federal Food, Drug, and Cosmetic Act that the primary mode of action of such product is that of a drug or biological product; or

(II) an applicable device clinical trial, if the Secretary determines under such section that the primary mode of action of such product is that of a device.

(3) EXPANSION OF REGISTRY DATA BANK TO INCLUDE RESULTS OF CLINICAL TRIALS.—

(A) LINKING REGISTRY DATA BANK TO EXISTING RESULTS.—

(i) IN GENERAL.—Beginning not later than 90 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, for those clinical trials that form the primary basis of an efficacy claim or are conducted after the drug involved is approved or after the device involved is cleared or approved, the Secretary shall ensure that the registry data bank includes links to results information as described in clause (ii) for such clinical trial—

(I) not earlier than 30 days after the date of the approval of the drug involved or clearance or approval of the device involved; or

(II) not later than 30 days after the results information described in clause (ii) becomes publicly available.

(ii) REQUIRED INFORMATION.—

(I) FDA INFORMATION.—The Secretary shall ensure that the registry data bank includes links to the following information:

(aa) If an advisory committee considered at a meeting an applicable clinical trial, any posted Food and Drug Administration summary document regarding such applicable clinical trial.

(bb) If an applicable drug clinical trial was conducted under section 505A or 505B of the Federal Food, Drug, and Cosmetic Act, a link to the posted Food and Drug Administration assessment of the results of such trial.

(cc) Food and Drug Administration public health advisories regarding the drug or device that is the subject of the applicable clinical trial, if any.

(dd) For an applicable drug clinical trial, the Food and Drug Administration action package for approval document required under section 505(l)(2) of the Federal Food, Drug, and Cosmetic Act.

(ee) For an applicable device clinical trial, in the case of a premarket application under section 515 of the Federal Food, Drug, and Cosmetic Act, the detailed summary of information respecting the safety and effectiveness of the device required under section 520(h)(1) of such Act, or, in the case of a report under section 510(k) of such Act, the section 510(k) summary of the safety and effectiveness data required under section 807.95(d) of title 21, Code of Federal Regulations (or any successor regulation).

(II) NIH INFORMATION.—The Secretary shall ensure that the registry data bank includes links to the following information:

(aa) Medline citations to any publications focused on the results of an applicable clinical trial.

(bb) The entry for the drug that is the subject of an applicable drug clinical trial in the National Library of Medicine database of structured product labels, if available.

(iii) RESULTS FOR EXISTING DATA BANK ENTRIES.—The Secretary may include the links described in clause (ii) for data bank entries for clinical trials submitted to the data bank prior to enactment of the Food

and Drug Administration Amendments Act of 2007, as available.

(B) INCLUSION OF RESULTS.—The Secretary, acting through the Director of NIH, shall—

(i) expand the registry data bank to include the results of applicable clinical trials (referred to in this subsection as the "registry and results data bank");

(ii) ensure that such results are made publicly available through the Internet;

(iii) post publicly a glossary for the lay public explaining technical terms related to the results of clinical trials; and

(iv) in consultation with experts on risk communication, provide information with the information included under subparagraph (C) in the registry and results data bank to help ensure that such information does not mislead the patients or the public.

(C) BASIC RESULTS.—Not later than 1 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall include in the registry and results data bank for each applicable clinical trial for a drug that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act or a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or 520(m) of such Act, the following elements:

(i) DEMOGRAPHIC AND BASELINE CHARACTERISTICS OF PATIENT SAMPLE.—A table of the demographic and baseline data collected overall and for each arm of the clinical trial to describe the patients who participated in the clinical trial, including the number of patients who dropped out of the clinical trial and the number of patients excluded from the analysis, if any.

(ii) PRIMARY AND SECONDARY OUTCOMES.—The primary and secondary outcome measures as submitted under paragraph (2)(A)(ii)(I)(ll), and a table of values for each of the primary and secondary outcome measures for each arm of the clinical trial, including the results of scientifically appropriate tests of the statistical significance of such outcome measures.

(iii) POINT OF CONTACT.—A point of contact for scientific information about the clinical trial results.

(iv) CERTAIN AGREEMENTS.—Whether there exists an agreement (other than an agreement solely to comply with applicable provisions of law protecting the privacy of participants) between the sponsor or its agent and the principal investigator (unless the sponsor is an employer of the principal investigator) that restricts in any manner the ability of the principal investigator, after the completion date of the trial, to discuss the results of the trial at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the trial.

(D) EXPANDED REGISTRY AND RESULTS DATA BANK.—

(i) EXPANSION BY RULEMAKING.—To provide more complete results information and to enhance patient access to and understanding of the results of clinical trials, not later than 3 years after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall by regulation expand the registry and results data bank as provided under this subparagraph.

(ii) CLINICAL TRIALS.—

(I) APPROVED PRODUCTS.—The regulations under this subparagraph shall require the inclusion of the results information described in clause (iii) for—

(aa) each applicable drug clinical trial for a drug that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act; and

(bb) each applicable device clinical trial for a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or 520(m) of such Act.

(II) UNAPPROVED PRODUCTS.—The regulations under this subparagraph shall establish whether or not the results information described in clause (iii) shall be required for—

(aa) an applicable drug clinical trial for a drug that is not approved under section 505 of the Federal Food, Drug, and Cosmetic Act and not licensed under section 351 of this Act (whether approval or licensure was sought or not); and

(bb) an applicable device clinical trial for a device that is not cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act and not approved under section 515 or section 520(m) of such Act (whether clearance or approval was sought or not).

(iii) REQUIRED ELEMENTS.—The regulations under this subparagraph shall require, in addition to the elements described in subparagraph (C), information within each of the following categories:

(I) A summary of the clinical trial and its results that is written in non-technical, understandable language for patients, if the Secretary determines that such types of summary can be included without being misleading or promotional.

(II) A summary of the clinical trial and its results that is technical in nature, if the Secretary determines that such types of summary can be included without being misleading or promotional.

(III) The full protocol or such information on the protocol for the trial as may be necessary to help to evaluate the results of the trial.

(IV) Such other categories as the Secretary determines appropriate.

(iv) RESULTS SUBMISSION.—The results information described in clause (iii) shall be submitted to the Director of NIH for inclusion in the registry and results data bank as provided by subparagraph (E), except that the Secretary shall by regulation determine—

(I) whether the 1-year period for submission of clinical trial information described in subparagraph (E)(i) should be increased from 1 year to a period not to exceed 18 months;

(II) whether the clinical trial information described in clause (iii) should be required to be submitted for an applicable clinical trial for which the clinical trial information described in subparagraph (C) is submitted to the registry and results data bank before the effective date of the regulations issued under this subparagraph; and

(III) in the case when the clinical trial information described in clause (iii) is required to be submitted for the applicable clinical trials described in clause (ii)(II), the date by which such clinical trial information shall be required to be submitted, taking into account—

(aa) the certification process under subparagraph (E)(iii) when approval, licensure, or clearance is sought; and

(bb) whether there should be a delay of submission when approval, licensure, or clearance will not be sought.

(v) ADDITIONAL PROVISIONS.—The regulations under this subparagraph shall also establish—

(I) a standard format for the submission of clinical trial information under this paragraph to the registry and results data bank;

(II) additional information on clinical trials and results that is written in nontechnical, understandable language for patients;

(III) considering the experience under the pilot quality control project described in paragraph (5)(C), procedures for quality control, including using representative samples, with respect to completeness and content of clinical trial information under this subsection, to help ensure that data elements are not false or misleading and are nonpromotional;

(IV) the appropriate timing and requirements for updates of clinical trial information, and whether and, if so, how such updates should be tracked;

(V) a statement to accompany the entry for an applicable clinical trial when the primary and secondary outcome measures for such clinical trial are submitted under paragraph (4)(A) after the

date specified for the submission of such information in paragraph (2)(C); and

(VI) additions or modifications to the manner of reporting of the data elements established under subparagraph (C).

(vi) CONSIDERATION OF WORLD HEALTH ORGANIZATION DATA SET.—The Secretary shall consider the status of the consensus data elements set for reporting clinical trial results of the World Health Organization when issuing the regulations under this subparagraph.

(vii) PUBLIC MEETING.—The Secretary shall hold a public meeting no later than 18 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007 to provide an opportunity for input from interested parties with regard to the regulations to be issued under this subparagraph.

(E) SUBMISSION OF RESULTS INFORMATION.—

(i) IN GENERAL.—Except as provided in clauses (iii), (iv), (v), and (vi) the responsible party for an applicable clinical trial that is described in clause (ii) shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraph (C) not later than 1 year, or such other period as may be provided by regulation under subparagraph (D), after the earlier of—

(I) the estimated completion date of the trial as described in paragraph (2)(A)(ii)(I)(jj)); or

(II) the actual date of completion.

(ii) CLINICAL TRIALS DESCRIBED.—An applicable clinical trial described in this clause is an applicable clinical trial subject to—

(I) paragraph (2)(C); and

(II)(aa) subparagraph (C); or

(bb) the regulations issued under subparagraph (D).

(iii) DELAYED SUBMISSION OF RESULTS WITH CERTIFICATION.—If the responsible party for an applicable clinical trial submits a certification that clause (iv) or (v) applies to such clinical trial, the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) as required under the applicable clause.

(iv) SEEKING INITIAL APPROVAL OF A DRUG OR DEVICE.—With respect to an applicable clinical trial that is completed before the drug is initially approved under section 505 of the Federal Food, Drug, and Cosmetic Act or initially licensed under section 351 of this Act, or the device is initially cleared under section 510(k) or initially approved under section 515 or 520(m) of the Federal Food, Drug, and Cosmetic Act, the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in sub-

paragraphs (C) and (D) not later than 30 days after the drug or device is approved under such section 505, licensed under such section 351, cleared under such section 510(k), or approved under such section 515 or 520(m), as applicable.

(v) SEEKING APPROVAL OF A NEW USE FOR THE DRUG OR DEVICE.—

(I) IN GENERAL.—With respect to an applicable clinical trial where the manufacturer of the drug or device is the sponsor of an applicable clinical trial, and such manufacturer has filed, or will file within 1 year, an application seeking approval under section 505 of the Federal Food, Drug, and Cosmetic Act, licensing under section 351 of this Act, or clearance under section 510(k), or approval under section 515 or 520(m), of the Federal Food, Drug, and Cosmetic Act for the use studied in such clinical trial (which use is not included in the labeling of the approved drug or device), then the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) on the earlier of the date that is 30 days after the date—

(aa) the new use of the drug or device is approved under such section 505, licensed under such section 351, cleared under such section 510(k), or approved under such section 515 or 520(m);

(bb) the Secretary issues a letter, such as a complete response letter, not approving the submission or not clearing the submission, a not approvable letter, or a not substantially equivalent letter for the new use of the drug or device under such section 505, 351, 510(k), 515, or 520(m); or

(cc) except as provided in subclause (III), the application or premarket notification under such section 505, 351, 510(k), 515, or 520(m) is withdrawn without resubmission for no less than 210 days.

(II) REQUIREMENT THAT EACH CLINICAL TRIAL IN APPLICATION BE TREATED THE SAME.—If a manufacturer makes a certification under clause (iii) that this clause applies with respect to a clinical trial, the manufacturer shall make such a certification with respect to each applicable clinical trial that is required to be submitted in an application or report for licensure, approval, or clearance (under section 351 of this Act or section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act, as applicable) of the use studied in the clinical trial.

(III) TWO-YEAR LIMITATION.—The responsible party shall submit to the Director of NIH for in-

clusion in the registry and results data bank the clinical trial information subject to subclause (I) on the date that is 2 years after the date a certification under clause (iii) was made to the Director of NIH, if an action referred to in item (aa), (bb), or (cc) of subclause (I) has not occurred by such date.

(vi) EXTENSIONS.—The Director of NIH may provide an extension of the deadline for submission of clinical trial information under clause (i) if the responsible party for the trial submits to the Director a written request that demonstrates good cause for the extension and provides an estimate of the date on which the information will be submitted. The Director of NIH may grant more than one such extension for a clinical trial.

(F) NOTICE TO DIRECTOR OF NIH.—The Commissioner of Food and Drugs shall notify the Director of NIH when there is an action described in subparagraph (E)(iv) or item (aa), (bb), or (cc) of subparagraph (E)(v)(I) with respect to an application or a report that includes a certification required under paragraph (5)(B) of such action not later than 30 days after such action.

(G) POSTING OF DATA.—The Director of NIH shall ensure that the clinical trial information described in subparagraphs (C) and (D) for an applicable clinical trial submitted in accordance with this paragraph is posted publicly in the registry and results database not later than 30 days after such submission.

(H) WAIVERS REGARDING CERTAIN CLINICAL TRIAL RESULTS.—The Secretary may waive any applicable requirements of this paragraph for an applicable clinical trial, upon a written request from the responsible party, if the Secretary determines that extraordinary circumstances justify the waiver and that providing the waiver is consistent with the protection of public health, or in the interest of national security. Not later than 30 days after any part of a waiver is granted, the Secretary shall notify, in writing, the appropriate committees of Congress of the waiver and provide an explanation for why the waiver was granted.

(I) ADVERSE EVENTS.—

(i) REGULATIONS.—Not later than 18 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall by regulation determine the best method for including in the registry and results data bank appropriate results information on serious adverse and frequent adverse events for applicable clinical trials described in subparagraph (C) in a manner and form that is useful and not misleading to patients, physicians, and scientists.

(ii) DEFAULT.—If the Secretary fails to issue the regulation required by clause (i) by the date that is 24 months after the date of the enactment of the Food

and Drug Administration Amendments Act of 2007, clause (iii) shall take effect.

(iii) ADDITIONAL ELEMENTS.—Upon the application of clause (ii), the Secretary shall include in the registry and results data bank for applicable clinical trials described in subparagraph (C), in addition to the clinical trial information described in subparagraph (C), the following elements:

(I) SERIOUS ADVERSE EVENTS.—A table of anticipated and unanticipated serious adverse events grouped by organ system, with number and frequency of such event in each arm of the clinical trial.

(II) FREQUENT ADVERSE EVENTS.—A table of anticipated and unanticipated adverse events that are not included in the table described in subclause (I) that exceed a frequency of 5 percent within any arm of the clinical trial, grouped by organ system, with number and frequency of such event in each arm of the clinical trial.

(iv) POSTING OF OTHER INFORMATION.—In carrying out clause (iii), the Secretary shall, in consultation with experts in risk communication, post with the tables information to enhance patient understanding and to ensure such tables do not mislead patients or the lay public.

(v) RELATION TO SUBPARAGRAPH (C).—Clinical trial information included in the registry and results data bank pursuant to this subparagraph is deemed to be clinical trial information included in such data bank pursuant to subparagraph (C).

(4) ADDITIONAL SUBMISSIONS OF CLINICAL TRIAL INFORMATION.—

(A) VOLUNTARY SUBMISSIONS.—A responsible party for a clinical trial that is not an applicable clinical trial, or that is an applicable clinical trial that is not subject to paragraph (2)(C), may submit complete clinical trial information described in paragraph (2) or paragraph (3) provided the responsible party submits clinical trial information for each applicable clinical trial that is required to be submitted under section 351 or under section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act in an application or report for licensure, approval, or clearance of the drug or device for the use studied in the clinical trial.

(B) REQUIRED SUBMISSIONS.—

(i) IN GENERAL.—Notwithstanding paragraphs (2) and (3) and subparagraph (A), in any case in which the Secretary determines for a specific clinical trial described in clause (ii) that posting in the registry and results data bank of clinical trial information for such clinical trial is necessary to protect the public health—

(I) the Secretary may require by notification that such information be submitted to the Sec-

retary in accordance with paragraphs (2) and (3) except with regard to timing of submission;

(II) unless the responsible party submits a certification under paragraph (3)(E)(iii), such information shall be submitted not later than 30 days after the date specified by the Secretary in the notification; and

(III) failure to comply with the requirements under subclauses (I) and (II) shall be treated as a violation of the corresponding requirement of such paragraphs.

(ii) CLINICAL TRIALS DESCRIBED.—A clinical trial described in this clause is—

(I) an applicable clinical trial for a drug that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act or for a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or section 520(m) of such Act, whose completion date is on or after the date 10 years before the date of the enactment of the Food and Drug Administration Amendments Act of 2007; or

(II) an applicable clinical trial that is described by both by paragraph (2)(C) and paragraph (3)(D)(ii)(II)).

(C) UPDATES TO CLINICAL TRIAL DATA BANK.—

(i) SUBMISSION OF UPDATES.—The responsible party for an applicable clinical trial shall submit to the Director of NIH for inclusion in the registry and results data bank updates to reflect changes to the clinical trial information submitted under paragraph (2). Such updates—

(I) shall be provided not less than once every 12 months, unless there were no changes to the clinical trial information during the preceding 12-month period;

(II) shall include identification of the dates of any such changes;

(III) not later than 30 days after the recruitment status of such clinical trial changes, shall include an update of the recruitment status; and

(IV) not later than 30 days after the completion date of the clinical trial, shall include notification to the Director that such clinical trial is complete.

(ii) PUBLIC AVAILABILITY OF UPDATES.—The Director of NIH shall make updates submitted under clause (i) publicly available in the registry data bank. Except with regard to overall recruitment status, individual site status, location, and contact information, the Director of NIH shall ensure that updates to elements required under subclauses (I) to (V) of paragraph (2)(A)(ii) do not result in the removal of any information from the original submissions or any preceding updates, and information in such databases is pre-

sented in a manner that enables users to readily access each original element submission and to track the changes made by the updates. The Director of NIH shall provide a link from the table of primary and secondary outcomes required under paragraph (3)(C)(ii) to the tracked history required under this clause of the primary and secondary outcome measures submitted under paragraph (2)(A)(ii)(I)(ll).

(5) COORDINATION AND COMPLIANCE.—

(A) CLINICAL TRIALS SUPPORTED BY GRANTS FROM FEDERAL AGENCIES.—

(i) GRANTS FROM CERTAIN FEDERAL AGENCIES.—If an applicable clinical trial is funded in whole or in part by a grant from any agency of the Department of Health and Human Services, including the Food and Drug Administration, the National Institutes of Health, or the Agency for Healthcare Research and Quality, any grant or progress report forms required under such grant shall include a certification that the responsible party has made all required submissions to the Director of NIH under paragraphs (2) and (3).

(ii) VERIFICATION BY FEDERAL AGENCIES.—The heads of the agencies referred to in clause (i), as applicable, shall verify that the clinical trial information for each applicable clinical trial for which a grantee is the responsible party has been submitted under paragraphs (2) and (3) before releasing any remaining funding for a grant or funding for a future grant to such grantee.

(iii) NOTICE AND OPPORTUNITY TO REMEDY.—If the head of an agency referred to in clause (i), as applicable, verifies that a grantee has not submitted clinical trial information as described in clause (ii), such agency head shall provide notice to such grantee of such non-compliance and allow such grantee 30 days to correct such non-compliance and submit the required clinical trial information.

(iv) CONSULTATION WITH OTHER FEDERAL AGENCIES.—The Secretary shall—

(I) consult with other agencies that conduct research involving human subjects in accordance with any section of part 46 of title 45, Code of Federal Regulations (or any successor regulations), to determine if any such research is an applicable clinical trial; and

(II) develop with such agencies procedures comparable to those described in clauses (i), (ii), and (iii) to ensure that clinical trial information for such applicable clinical trial is submitted under paragraphs (2) and (3).

(B) CERTIFICATION TO ACCOMPANY DRUG, BIOLOGICAL PRODUCT, AND DEVICE SUBMISSIONS.—At the time of submission of an application under section 505 of the Federal Food, Drug, and Cosmetic Act, section 515 of such Act, section 520(m) of such Act, or section 351 of this Act, or submission of a report under section 510(k) of such Act, such

application or submission shall be accompanied by a certification that all applicable requirements of this subsection have been met. Where available, such certification shall include the appropriate National Clinical Trial control numbers.

(C) QUALITY CONTROL.—

(i) PILOT QUALITY CONTROL PROJECT.—Until the effective date of the regulations issued under paragraph (3)(D), the Secretary, acting through the Director of NIH and the Commissioner of Food and Drugs, shall conduct a pilot project to determine the optimal method of verification to help to ensure that the clinical trial information submitted under paragraph (3)(C) is non-promotional and is not false or misleading in any particular under subparagraph (D). The Secretary shall use the publicly available information described in paragraph (3)(A) and any other information available to the Secretary about applicable clinical trials to verify the accuracy of the clinical trial information submitted under paragraph (3)(C).

(ii) NOTICE OF COMPLIANCE.—If the Secretary determines that any clinical trial information was not submitted as required under this subsection, or was submitted but is false or misleading in any particular, the Secretary shall notify the responsible party and give such party an opportunity to remedy such noncompliance by submitting the required revised clinical trial information not later than 30 days after such notification.

(D) TRUTHFUL CLINICAL TRIAL INFORMATION.—

(i) IN GENERAL.—The clinical trial information submitted by a responsible party under this subsection shall not be false or misleading in any particular.

(ii) EFFECT.—Clause (i) shall not have the effect of—

(I) requiring clinical trial information with respect to an applicable clinical trial to include information from any source other than such clinical trial involved; or

(II) requiring clinical trial information described in paragraph (3)(D) to be submitted for purposes of paragraph (3)(C).

(E) PUBLIC NOTICES.—

(i) NOTICE OF VIOLATIONS.—If the responsible party for an applicable clinical trial fails to submit clinical trial information for such clinical trial as required under paragraphs (2) or (3), the Director of NIH shall include in the registry and results data bank entry for such clinical trial a notice—

(I) that the responsible party is not in compliance with this Act by—

(aa) failing to submit required clinical trial information; or

(bb) submitting false or misleading clinical trial information;

(II) of the penalties imposed for the violation, if any; and

(III) whether the responsible party has corrected the clinical trial information in the registry and results data bank.

(ii) NOTICE OF FAILURE TO SUBMIT PRIMARY AND SECONDARY OUTCOMES.—If the responsible party for an applicable clinical trial fails to submit the primary and secondary outcomes as required under section 2(A)(ii)(I)(ll), the Director of NIH shall include in the registry and results data bank entry for such clinical trial a notice that the responsible party is not in compliance by failing to register the primary and secondary outcomes in accordance with this act, and that the primary and secondary outcomes were not publicly disclosed in the database before conducting the clinical trial.

(iii) FAILURE TO SUBMIT STATEMENT.—The notice under clause (i) for a violation described in clause (i)(I)(aa) shall include the following statement: "The entry for this clinical trial was not complete at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.".

(iv) SUBMISSION OF FALSE INFORMATION STATEMENT.—The notice under clause (i) for a violation described in clause (i)(I)(bb) shall include the following statement: "The entry for this clinical trial was found to be false or misleading and therefore not in compliance with the law.".

(v) NON-SUBMISSION OF STATEMENT.—The notice under clause (ii) for a violation described in clause (ii) shall include the following statement: "The entry for this clinical trial did not contain information on the primary and secondary outcomes at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.".

(vi) COMPLIANCE SEARCHES.—The Director of NIH shall provide that the public may easily search the registry and results data bank for entries that include notices required under this subparagraph.

(6) LIMITATION ON DISCLOSURE OF CLINICAL TRIAL INFORMATION.—

(A) IN GENERAL.—Nothing in this subsection (or under section 552 of title 5, United States Code) shall require the Secretary to publicly disclose, by any means other than the registry and results data bank, information described in subparagraph (B).

(B) INFORMATION DESCRIBED.—Information described in this subparagraph is—

(i) information submitted to the Director of NIH under this subsection, or information of the same general nature as (or integrally associated with) the information so submitted; and

(ii) information not otherwise publicly available, including because it is protected from disclosure under section 552 of title 5, United States Code.

(7) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection $10,000,000 for each fiscal year.

(k)(1) The Director of NIH may establish a program to provide day care services for the employees of the National Institutes of Health similar to those services provided by other Federal agencies (including the availability of day care service on a 24-hour-a-day basis).

(2) Any day care provider at the National Institutes of Health shall establish a sliding scale of fees that takes into consideration the income and needs of the employee.

(3) For purposes regarding the provision of day care services, the Director of NIH may enter into rental or lease purchase agreements.

(l) COUNCIL OF COUNCILS.—

(1) ESTABLISHMENT.—Not later than 90 days after the date of the enactment of the National Institutes of Health Reform Act of 2006, the Director of NIH shall establish within the Office of the Director an advisory council to be known as the "Council of Councils" (referred to in this subsection as the "Council") for the purpose of advising the Director on matters related to the policies and activities of the Division of Program Coordination, Planning, and Strategic Initiatives, including making recommendations with respect to the conduct and support of research described in subsection (b)(7).

(2) MEMBERSHIP.—

(A) IN GENERAL.—The Council shall be composed of 27 members selected by the Director of NIH with approval from the Secretary from among the list of nominees under subparagraph (C).

(B) CERTAIN REQUIREMENTS.—In selecting the members of the Council, the Director of NIH shall ensure—

(i) the representation of a broad range of disciplines and perspectives; and

(ii) the ongoing inclusion of at least 1 representative from each national research institute whose budget is substantial relative to a majority of the other institutes.

(C) NOMINATION.—The Director of NIH shall maintain an updated list of individuals who have been nominated to serve on the Council, which list shall consist of the following:

(i) For each national research institute and national center, 3 individuals nominated by the head of such institute or center from among the members of the advisory council of the institute or center, of which—

(I) two shall be scientists; and

(II) one shall be from the general public or shall be a leader in the field of public policy, law, health policy, economics, or management.

(ii) For each office within the Division of Program Coordination, Planning, and Strategic Initiatives, 1 individual nominated by the head of such office.

(iii) Members of the Council of Public Representatives.

(3) TERMS.—

(A) IN GENERAL.—The term of service for a member of the Council shall be 6 years, except as provided in subparagraphs (B) and (C).

(B) TERMS OF INITIAL APPOINTEES.—Of the initial members selected for the Council, the Director of NIH shall designate—

(i) nine for a term of 6 years;

(ii) nine for a term of 4 years; and

(iii) nine for a term of 2 years.

(C) VACANCIES.—Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has taken office.

(m) NATIONAL INSTITUTES OF HEALTH STRATEGIC PLAN.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of the 21st Century Cures Act, and at least every 6 years thereafter, the Director of the National Institutes of Health shall develop and submit to the appropriate committees of Congress and post on the Internet website of the National Institutes of Health, a coordinated strategy (to be known as the "National Institutes of Health Strategic Plan") to provide direction to the biomedical research investments made by the National Institutes of Health, to facilitate collaboration across the institutes and centers, to leverage scientific opportunity, and to advance biomedicine.

(2) REQUIREMENTS.—The strategy under paragraph (1) shall—

(A) identify strategic research priorities and objectives across biomedical research, including—

(i) an assessment of the state of biomedical and behavioral research, including areas of opportunity with respect to basic, clinical, and translational research;

(ii) priorities and objectives to advance the treatment, cure, and prevention of health conditions;

(iii) emerging scientific opportunities, rising public health challenges, and scientific knowledge gaps; and

(iv) the identification of near-, mid-, and long-term scientific needs;

(B) consider, in carrying out subparagraph (A)—

(i) disease burden in the United States and the potential for return on investment to the United States;

(ii) rare diseases and conditions;

(iii) biological, social, and other determinants of health that contribute to health disparities; and

(iv) other factors the Director of National Institutes of Health determines appropriate;

(C) include multi-institute priorities, including coordination of research among institutes and centers;

(D) include strategic priorities for funding research through the Common Fund, in accordance with section 402A(c)(1)(C);

(E) address the National Institutes of Health's proposed and ongoing activities related to training and the biomedical workforce; and

(F) describe opportunities for collaboration with other agencies and departments, as appropriate.

(3) USE OF PLANS.—Strategic plans developed and updated by the national research institutes and national centers of the National Institutes of Health shall be prepared regularly and in such a manner that such plans will be informed by the strategic plans developed and updated under this subsection. Such plans developed by and updated by the national research institutes and national centers shall have a common template.

(4) CONSULTATION.—The Director of National Institutes of Health shall develop the strategic plan under paragraph (1) in consultation with the directors of the national research institutes and national centers, researchers, patient advocacy groups, and industry leaders.

(n) UNIQUE RESEARCH INITIATIVES.—

(1) IN GENERAL.—The Director of NIH may approve, after consideration of a proposal under paragraph (2)(A), requests by the national research institutes and centers, or program officers within the Office of the Director to engage in transactions other than a contract, grant, or cooperative agreement with respect to projects that carry out—

(A) the Precision Medicine Initiative under section 498E;

(B) section 402(b)(7), except that not more than 50 percent of the funds available for a fiscal year through the Common Fund under section 402A(c)(1) for purposes of carrying out such section 402(b)(7) may be used to engage in such other transactions; or

(C) high impact cutting-edge research that fosters scientific creativity and increases fundamental biological understanding leading to the prevention, diagnosis, or treatment of diseases and disorders, or research urgently required to respond to a public health threat.

(2) REQUIREMENTS.—The authority provided under this subsection may be used to conduct or support high impact cutting-edge research described in paragraph (1) using the other transactions authority described in such paragraph if the institute, center, or office—

(A) submits a proposal to the Director of NIH for the use of such authority before conducting or supporting the research, including why the use of such authority is essential to promoting the success of the project;

(B) receives approval for the use of such authority from the Director of NIH; and

(C) for each year in which the institute, center, or office has used such authority in accordance with this subsection, submits a report to the Director of NIH on the ac-

tivities of the institute, center, or office relating to such research.

(o) REGENERATIVE MEDICINE.—The Director of NIH shall, as appropriate, continue to consult with the directors of relevant institutes and centers of the National Institutes of Health, other relevant experts from such institutes and centers, and relevant experts within the Food and Drug Administration, to further the field of regenerative medicine using adult stem cells, including autologous stem cells, therapeutic tissue engineering products, human cell and tissue products, human gene therapies, and genetically modified cells.

SEC. 402A. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—

(1) THIS TITLE.—For purposes of carrying out this title, there are authorized to be appropriated—

(A) $30,331,309,000 for fiscal year 2007;
(B) $32,831,309,000 for fiscal year 2008;
(C) such sums as may be necessary for fiscal year 2009;
(D) $34,851,000,000 for fiscal year 2018;
(E) $35,585,871,000 for fiscal year 2019; and
(F) $36,472,442,775 for fiscal year 2020.

(2) FUNDING FOR [10-YEAR] PEDIATRIC RESEARCH INITIATIVE [THROUGH COMMON FUND].—For the purpose of carrying out section 402(b)(7)(B)(ii), there is authorized to be appropriated [to the Common Fund] *to the Division of Program Coordination, Planning, and Strategic Initiatives*, out of the [10-Year] Pediatric Research Initiative Fund described in section 9008 of the Internal Revenue Code of 1986, and in addition to amounts otherwise made available under paragraph (1) of this subsection [and reserved under subsection (c)(1)(B)(i) of this section], $12,600,000 for each of fiscal years [2014 through 2023] *2024 through 2028*.

(b) OFFICE OF THE DIRECTOR.—Of the amount authorized to be appropriated under subsection (a) for a fiscal year, there are authorized to be appropriated for programs and activities under this title carried out through the Office of the Director of NIH such sums as may be necessary for each of the fiscal years 2007 through 2009.

(c) TRANS-NIH RESEARCH.—

(1) COMMON FUND.—

(A) ACCOUNT.—For the purpose of allocations under [section 402(b)(7)(B)] *section 402(b)(7)(B)(i)* (relating to research identified by the Division of Program Coordination, Planning, and Strategic Initiatives), there is established an account to be known as the Common Fund.

(B) RESERVATION.—

(i) IN GENERAL.—Of the total amount appropriated under subsection (a)(1) for fiscal year 2007 or any subsequent fiscal year, the Director of NIH shall reserve an amount for the Common Fund, subject to any applicable provisions in appropriations Acts.

(ii) MINIMUM AMOUNT.—For each fiscal year, the percentage constituted by the amount reserved under clause (i) relative to the total amount appropriated under subsection (a)(1) for such year may not be less

than the percentage constituted by the amount so reserved for the preceding fiscal year relative to the total amount appropriated under subsection (a)(1) for such preceding fiscal year, subject to any applicable provisions in appropriations Acts.

(C) COMMON FUND STRATEGIC PLANNING REPORT.—As part of the National Institutes of Health Strategic Plan required under section 402(m), the Secretary, acting through the Director of NIH, shall submit a report to the Congress containing a strategic plan for funding research described in section 402(b)(7)(A)(i) (including personnel needs) through the Common Fund. Each such plan shall include the following:

(i) An estimate of the amounts determined by the Director of NIH to be appropriate for maximizing the potential of such research.

(ii) An estimate of the amounts determined by the Director of NIH to be sufficient only for continuing to fund research activities previously identified by the Division of Program Coordination, Planning, and Strategic Initiatives.

(iii) An estimate of the amounts determined by the Director of NIH to be necessary to fund research described in section 402(b)(7)(A)(i)—

(I) that is in addition to the research activities described in clause (ii); and

(II) for which there is the most substantial need.

(D) EVALUATION.—During the 6-month period following the end of the first fiscal year for which the total amount reserved under subparagraph (B) is equal to 5 percent of the total amount appropriated under subsection (a)(1) for such fiscal year, the Secretary, acting through the Director of NIH, in consultation with the advisory council established under section 402(k), shall submit recommendations to the Congress for changes regarding amounts for the Common Fund.

(2) TRANS-NIH RESEARCH REPORTING.—

(A) LIMITATION.—With respect to the total amount appropriated under subsection (a) for fiscal year 2008 or any subsequent fiscal year, if the head of a national research institute or national center fails to submit the report required by subparagraph (B) for the preceding fiscal year, the amount made available for the institute or center for the fiscal year involved may not exceed the amount made available for the institute or center for fiscal year 2006.

(B) REPORTING.—Not later than 2 years after the date of enactment of 21st Century Cures Act, the head of each national research institute or national center shall submit to the Director of the National Institutes of Health a report, to be included in the triennial report under section 403, on the amount made available by the institute or center for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers.

(C) DETERMINATION.—For purposes of determining the amount or percentage of funds to be reported under subparagraph (B), any amounts made available to an institute or center under [section 402(b)(7)(B)] *section 402(b)(7)(B)(i)* shall be included.

(D) VERIFICATION OF AMOUNTS.—Upon receipt of each report submitted under subparagraph (B), the Director of NIH shall review and, in cases of discrepancy, verify the accuracy of the amounts specified in the report.

(E) WAIVER.—At the request of any national research institute or national center, the Director of NIH may waive the application of this paragraph to such institute or center if the Director finds that the conduct or support of research described in subparagraph (B) is inconsistent with the mission of such institute or center.

(d) TRANSFER AUTHORITY.—Of the total amount appropriated under subsection (a)(1) for a fiscal year, the Director of NIH may (in addition to the reservation under subsection (c)(1) for such year) transfer not more than 1 percent for programs or activities that are authorized in this title and identified by the Director to receive funds pursuant to this subsection. In making such transfers, the Director may not decrease any appropriation account under subsection (a)(1) by more than 1 percent.

(e) RULE OF CONSTRUCTION.—This section may not be construed as affecting the authorities of the Director of NIH under section 401.

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