

112TH CONGRESS
1ST SESSION

H. R. 2625

To amend the Public Health Service Act with respect to human subject research to improve protections for human subjects and, where appropriate because of the type research involved, to reduce regulatory burdens.

IN THE HOUSE OF REPRESENTATIVES

JULY 22, 2011

Ms. DEGETTE introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act with respect to human subject research to improve protections for human subjects and, where appropriate because of the type research involved, to reduce regulatory burdens.

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 “Research Participants
5 Protection Modernization Act of 2011”.

1 **SEC. 2. PROTECTION OF HUMAN SUBJECTS IN RESEARCH;**
2 **APPLICABILITY OF RULES.**

3 Part H of title IV of the Public Health Service Act
4 (42 U.S.C. 289 et seq.) is amended by inserting after sec-
5 tion 491 the following section:

6 **“SEC. 491A. PROTECTION OF HUMAN SUBJECTS IN RE-**
7 **SEARCH; APPLICABILITY OF RULES.**

8 “(a) PROTECTION OF HUMAN SUBJECTS.—

9 “(1) IN GENERAL.—Except as provided in para-
10 graph (2), all human subject research described in
11 paragraph (3)(A) shall be conducted in accordance
12 with the HHS Human Subject Regulations, and as
13 applicable to the human subjects involved in such re-
14 search, with the vulnerable-populations rules.

15 “(2) FDA RESEARCH.—

16 “(A) APPLICABLE RULES.—All human
17 subject research that is subject to the Federal
18 Food, Drug, and Cosmetic Act or to section
19 351 of this Act shall be conducted—

20 “(i) in accordance with the provisions
21 of parts 50, 56, 312, and 812 of title 21,
22 Code of Federal Regulations (or any suc-
23 cessor regulations); and

24 “(ii) as applicable to the human sub-
25 jects involved in such research, in accord-
26 ance with provisions applicable to vulner-

1 able populations under part 56 of such
2 title 21 (or any successor regulations) and
3 subpart D of part 50 of such title 21 (or
4 any successor regulations).

5 “(B) REFERENCES.—In the case of human
6 subject research described in subparagraph
7 (A)—

8 “(i) each reference in this section or
9 section 491B to the HHS Human Subject
10 Regulations shall be treated as a reference
11 to the provisions described in subpara-
12 graph (A)(i); and

13 “(ii) each reference in this section to
14 the vulnerable population rules shall be
15 treated as a reference to the provisions de-
16 scribed in subparagraph (A)(ii).

17 “(3) APPLICABILITY.—

18 “(A) IN GENERAL.—This section applies to
19 human subject research that is—

20 “(i) conducted or supported by the
21 Department of Health and Human Serv-
22 ices; or

23 “(ii) otherwise subject to regulation
24 by the Department under a provision of
25 Federal law (other than this section).

1 “(B) OTHER FEDERAL DEPARTMENTS AND
2 AGENCIES.—The Secretary shall make available
3 assistance to any Federal department or agency
4 seeking—

5 “(i) to improve the regulation or over-
6 sight of human subject research; or

7 “(ii) to apply the HHS Human Sub-
8 ject Regulations or the vulnerable-popu-
9 lation rules to human subject research that
10 is conducted, supported, or regulated by
11 such department or agency.

12 “(b) HHS HUMAN SUBJECT REGULATIONS; OTHER
13 DEFINITIONS.—

14 “(1) HHS HUMAN SUBJECT REGULATIONS;
15 VULNERABLE-POPULATION RULES.—For purposes of
16 this section:

17 “(A) Except as provided in subsection
18 (a)(2)(B) (relating to FDA research), the term
19 ‘HHS Human Subject Regulations’ means the
20 provisions of subpart A of part 46 of title 45,
21 Code of Federal Regulations (or any successor
22 regulations).

23 “(B) Except as provided in subsection
24 (a)(2)(B) (relating to FDA research), the term
25 ‘vulnerable-population rules’ means the provi-

1 sions of subparts B through D of such part 46
2 (or any successor regulations).

3 “(2) HUMAN SUBJECT RESEARCH.—For pur-
4 poses of this section:

5 “(A) Except as provided in subparagraph
6 (B), the term ‘human subject research’ means
7 research, as defined in subpart A of part 46 of
8 title 45, Code of Federal Regulations (or any
9 successor regulations), that involves a human
10 subject, as defined in such subpart A (or any
11 successor regulations).

12 “(B) In the case of an investigation that is
13 subject to the provisions of part 50 of title 21,
14 Code of Federal Regulations (or successor regu-
15 lations), the term ‘human subject’ has the
16 meaning given such term in such part 50, and
17 the term ‘human subject research’ means a clin-
18 ical investigation as defined in such part 50.

19 “(3) OTHER DEFINITIONS.—For purposes of
20 this section:

21 “(A) The terms ‘institution served by an
22 institutional review board’ and ‘institution
23 served by the board’ mean the public or private
24 entity (university, health care provider, health
25 plan, research organization, government agency,

1 independent institutional review board, or other
2 entity) that establishes and is responsible for
3 the operation of the institutional review board.

4 “(B) The term ‘institutional review board’
5 has the meaning that applies to the term ‘insti-
6 tutional review board’ under the HHS Human
7 Subject Regulations.

8 “(C) The term ‘lead institutional review
9 board’ means an institutional review board that
10 otherwise meets the requirements of the HHS
11 Human Subject Regulations and enters into a
12 written agreement with an institution, another
13 institutional review board, a sponsor, or a prin-
14 cipal investigator to approve and oversee human
15 subject research that is conducted at multiple
16 locations. For purposes of this section, ref-
17 erences to an institutional review board include
18 an institutional review board that serves a sin-
19 gle institution as well as a lead institutional re-
20 view board.

21 “(D) The term ‘principal investigator’,
22 with respect to human subject research, means
23 the individual who, at the research location in-
24 volved, has the principal responsibility for the
25 conduct of the research.

1 “(E)(i) Except as provided in clause (ii),
2 the term ‘sponsor’, with respect to human sub-
3 ject research, means the entity that provides
4 the majority or plurality of the financial sup-
5 port for the conduct of the research.

6 “(ii) In the case of an investigation that is
7 subject to the provisions of part 50 of title 21,
8 Code of Federal Regulations (or successor regu-
9 lations), the term ‘sponsor’, with respect to
10 human subject research, has the meaning that
11 applies for purposes of such part 50.

12 “(c) SCOPE OF AUTHORITY OF SECRETARY.—

13 “(1) IN GENERAL.—The HHS Human Subject
14 Regulations (including provisions regarding exemp-
15 tions) and the vulnerable-populations rules, as in ef-
16 fect on the day before the date of the enactment of
17 the Research Participants Protection Modernization
18 Act of 2011, continue to be in effect on and after
19 such date, subject to paragraph (2).

20 “(2) MODIFICATIONS.—

21 “(A) COMPLIANCE WITH LAW.—Promptly
22 after the date of the enactment of the Act re-
23 ferred to in paragraph (1), the Secretary shall
24 promulgate regulations to make such modifica-
25 tions to the provisions of the HHS Human

1 Subject Regulations as may be necessary to en-
2 sure that such provisions implement, and do not
3 conflict with, this section.

4 “(B) OTHER MODIFICATIONS.—This sec-
5 tion may not be construed as affecting the au-
6 thority of the Secretary to modify the provisions
7 of the HHS Human Subject Regulations or the
8 vulnerable-populations rules, except to the ex-
9 tent that any such modification is in conflict
10 with this section. Any such modification shall
11 be made by regulation.

12 “(C) CONSIDERATION OF CERTAIN MAT-
13 TERS.—

14 “(i) IN GENERAL.—The Secretary
15 shall, with respect to the HHS Human
16 Subject Regulations, consider the matters
17 specified in clause (iii) and make a deter-
18 mination of whether any of the provisions
19 of such Rule or any guidance associated
20 with such Rule should be modified accord-
21 ingly.

22 “(ii) TIMING.—The Secretary shall
23 publish the determination required by
24 clause (i) in the Federal Register—

1 “(I) except as provided in sub-
2 clause (II), not later than 3 years
3 after the date of the enactment of the
4 Research Participants Protection
5 Modernization Act of 2011; and

6 “(II) in the case of a determina-
7 tion on the matters specified in clause
8 (iii)(IX), not later than 18 months
9 after the submission of the report re-
10 quired by section 5 of the Research
11 Participants Protection Modernization
12 Act of 2011.

13 “(iii) LIST OF MATTERS FOR CONSID-
14 ERATION.—The matters referred to in
15 clause (i) with respect to the HHS Human
16 Subject Regulations are the following:

17 “(I) How requirements regarding
18 the definition and management of po-
19 tential financial conflict of interest,
20 including both investigator and insti-
21 tutional conflicts of interest, should be
22 strengthened and enforced to protect
23 human subjects more effectively.

24 “(II) Whether the list of exemp-
25 tions from applicability of the HHS

1 Human Subject Regulations, as in ef-
2 fect on the day before the date of en-
3 actment referred to in clause (ii)(I),
4 should be expanded to include new
5 categories.

6 “(III) Whether and under what
7 circumstances research that studies
8 human tissue or other types of clinical
9 specimens should not be considered a
10 clinical investigation.

11 “(IV) Whether the list of cat-
12 egories of research that are eligible
13 for expedited review under the HHS
14 Human Subject Regulations, as in ef-
15 fect on the day before the date of en-
16 actment referred to in clause (ii)(I),
17 should be expanded to include new
18 categories of research eligible for ex-
19 pedited review.

20 “(V) Whether institutional review
21 boards include sufficient numbers of
22 minority individuals as board mem-
23 bers when reviewing proposals de-
24 signed to include human subjects who
25 are minority individuals.

1 “(VI) Whether the requirements
2 for the number of members of an in-
3 stitutional review board who are indi-
4 viduals whose primary expertise is in
5 nonscientific areas, and the number of
6 members of an institutional review
7 board who are individuals who are not
8 affiliated with the institution served
9 by the board, should be increased.

10 “(VII) Whether institutional re-
11 view boards include sufficient num-
12 bers of individuals with appropriate
13 scientific expertise.

14 “(VIII) How to enhance the pro-
15 tection of people with diminished deci-
16 sionmaking capacity with respect to
17 their participation as subjects in
18 human subject research.

19 “(IX) How the requirements for
20 institutional review board review in
21 multisite research should be modified
22 to reduce regulatory burden while pro-
23 tecting human subjects, including use
24 of a lead institutional review board.

1 “(X) How the requirements for
2 managing and reporting adverse
3 events and unanticipated problems
4 should be modified—

5 “(aa) to increase consistency
6 between such requirements of the
7 Office for Human Research Pro-
8 tections of the Department of
9 Health and Human Services and
10 the corresponding requirements
11 of the Food and Drug Adminis-
12 tration; and

13 “(bb) to reduce regulatory
14 burden appropriately while pro-
15 tecting human subjects.

16 “(XI) How the requirements for
17 approval and oversight of human sub-
18 jects research that poses no more
19 than minimal risk to participants (in-
20 cluding requirements of informed con-
21 sent, documentation of informed con-
22 sent, and continuing review) should be
23 modified to reduce regulatory burden
24 (including burden on institutions, in-
25 stitutional review boards, and inves-

1 tigators) while protecting research
2 participants, including clarification of
3 the circumstances in which informed
4 consent does not need to be writing.

5 “(XII) Whether research that
6 would be defined as a ‘clinical inves-
7 tigation’ under part 50 of title 21,
8 Code of Federal Regulations, should
9 comply with the guideline published
10 by the Food and Drug Administration
11 and endorsed by the International
12 Conference on Harmonisation of
13 Technical Requirements for Registra-
14 tion of Pharmaceuticals for Human
15 Use, entitled ‘Good Clinical Practice:
16 Consolidated Guideline’, and how in-
17 vestigators can be educated effectively
18 regarding compliance with this guide-
19 line.

20 “(XIII) Such additional matters
21 as the Secretary determines to be ap-
22 propriate.

23 “(d) INSTITUTIONAL REVIEW BOARDS.—

24 “(1) NOTIFICATION OF INSTITUTIONAL REVIEW
25 BOARD AND SPONSORS BY INVESTIGATORS.—

1 “(A) REQUIREMENT.—In submitting to an
2 institutional review board a proposal for human
3 subject research, the investigators for the re-
4 search shall notify the institution served by the
5 board—

6 “(i) of any significant financial inter-
7 est, as defined by applicable Federal regu-
8 lations;

9 “(ii) whether the investigators have
10 been disqualified or restricted by any Fed-
11 eral, State, or local entity in their ability
12 to conduct human subject research, includ-
13 ing being ineligible to conduct human sub-
14 ject research with investigational new
15 drugs, being ineligible for approval of new
16 drug applications, or agreeing to some
17 other form of restriction regarding re-
18 search; and

19 “(iii) whether the proposal has been
20 submitted to any other institutional review
21 board and, as applicable, of any findings
22 made by such board.

23 “(B) TIMING.—A notification required by
24 subparagraph (A) shall be submitted to the in-
25 stitution served by the board—

1 “(i) at the time of submitting the pro-
2 posal for human subject research to the
3 board; or

4 “(ii) in the case of circumstances aris-
5 ing after such submission, immediately.

6 “(2) INSTITUTIONAL REVIEW OF CONFLICTS OF
7 INTEREST.—The institution served by an institu-
8 tional review board shall—

9 “(A) review such significant financial in-
10 terests as are submitted to the institution under
11 paragraph (1) to determine whether such inter-
12 ests create or may reasonably appear to create
13 conflicts of interest; and

14 “(B) seek to eliminate or manage such
15 conflicts of interest.

16 “(3) COST RECOVERY.—Institutions may re-
17 cover costs associated with compliance for human
18 subject protections under this part from government
19 sponsors of research as direct costs.

20 “(e) INSTITUTIONAL PROGRAMS OF EDUCATION.—
21 For fiscal year 2012 and subsequent fiscal years, the Sec-
22 retary may not make an award of a grant, cooperative
23 agreement, or contract under this Act to a public entity
24 or a private academic institution, or make an award of
25 a grant, cooperative agreement, or contract under this Act

1 for the conduct of research at or through or in affiliation
2 with a public entity or a private academic institution, un-
3 less the public entity or private academic institution (as
4 the case may be) maintains or contracts for a program
5 to educate investigators and board members on the protec-
6 tion of human subjects in research.

7 “(f) APPLICABILITY OF REQUIREMENTS.—The re-
8 quirements of this section apply on and after the date of
9 the enactment of the Research Participants Protection
10 Modernization Act of 2011.”.

11 **SEC. 3. OFFICE FOR HUMAN RESEARCH PROTECTIONS.**

12 (a) IN GENERAL.—Part H of title IV of the Public
13 Health Service Act (42 U.S.C. 289 et seq.), as amended
14 by section 2 of this Act, is amended by inserting after
15 section 491A the following section:

16 **“SEC. 491B. OFFICE FOR HUMAN RESEARCH PROTECTIONS.**

17 “(a) IN GENERAL.—There is established within the
18 office of the Secretary an office to be known as the Office
19 for Human Research Protections (in this section referred
20 to as the ‘Office’). The Office shall be headed by a direc-
21 tor, who shall be appointed by the Secretary. The Sec-
22 retary shall carry out this section acting through the Di-
23 rector of the Office.

24 “(b) CERTAIN DUTIES.—The Director of the Of-
25 fice—

1 “(1) shall provide for the protection of human
2 subjects in research by carrying out activities in ac-
3 cordance with section 491A;

4 “(2) shall establish criteria regarding assur-
5 ances of compliance with the requirements of section
6 491A;

7 “(3) shall direct activities within the Depart-
8 ment of Health and Human Services, and coordinate
9 the activities of the Department with other Federal
10 departments and agencies, with respect to the pro-
11 tection of subjects in human subject research;

12 “(4) may, in collaboration with the Director of
13 NIH, the Commissioner of Food and Drugs, or the
14 head of any other Federal department or agency,
15 carry out educational and quality improvement pro-
16 grams for human subject protections for principal
17 investigators, members of institutional review
18 boards, and other appropriate persons, including the
19 generation of resource materials relating to the re-
20 sponsibilities of the research community for the pro-
21 tection of human subjects in research;

22 “(5) shall, upon the request of an entity that
23 conducts or supports human subject research—

1 “(A) consult with the entity regarding im-
2 provements in human subject protections in
3 such research; and

4 “(B) provide advice on compliance with
5 section 491A, including with respect to differing
6 interpretations among institutional review
7 boards of a provision of such section;

8 “(6) may make grants to entities that conduct
9 or support human subject research for the purpose
10 of assisting the entities in carrying out programs to
11 recruit and train minority individuals to serve as
12 members of institutional review boards;

13 “(7) shall consult with experts in biomedical,
14 behavioral, and social sciences research in carrying
15 out the duties of the Director; and

16 “(8) shall carry out such additional authorities
17 of the Secretary regarding the protection of human
18 subjects in research as the Secretary determines to
19 be appropriate.

20 “(c) MODEL EDUCATION PROGRAMS.—The Director
21 of the Office may make grants for the development of
22 model education programs that may be used by institu-
23 tions served by institutional review boards to promote best
24 practices in institutional management of human subject
25 research.

1 “(d) FUNDING.—

2 “(1) AUTHORIZATION OF APPROPRIATIONS.—

3 For the purpose of carrying out this section, there
4 are authorized to be appropriated \$20,000,000 for
5 fiscal year 2012, and such sums as may be nec-
6 essary for fiscal year 2013 and each subsequent fis-
7 cal year.

8 “(2) MODEL EDUCATION PROGRAMS.—For the
9 purpose of carrying out subsection (c), there are au-
10 thorized to be appropriated such sums as may be
11 necessary for fiscal year 2012 and each subsequent
12 fiscal year.

13 “(3) RULE OF CONSTRUCTION.—Nothing in
14 this section or section 491A may be construed as a
15 change in the budget authority or authorization of
16 appropriations for the Food and Drug Administra-
17 tion.”.

18 (b) FUNCTIONS, PERSONNEL, ASSETS, AND LIABIL-
19 ITIES.—All functions, personnel, assets, and liabilities of
20 the Office for Human Research Protection of the Depart-
21 ment of Health and Human Services, as in existence on
22 the day before the date of the enactment of this Act, shall
23 be transferred to the Office for Human Research Protec-
24 tions established by section 491B of the Public Health
25 Service Act, as added by subsection (a).

1 **SEC. 4. AMENDMENTS REGARDING PROCESS FOR RE-**
2 **SPONDING TO REPORTS OF VIOLATIONS.**

3 Section 491(b)(2) of the Public Health Service Act
4 (42 U.S.C. 289(b)(2)) is amended—

5 (1) in the first sentence, by inserting “or the
6 Director of the Office for Human Research Protec-
7 tions” after “the Director of NIH”; and

8 (2) in the second sentence, by inserting after
9 “this Act” the following: “, sharing of information
10 between the Director of NIH and the Director of
11 such Office,”.

○