

110TH CONGRESS
2^D SESSION

H. R. 7140

To amend the Public Health Service Act with respect to the protection of human subjects in research.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 26, 2008

Ms. DEGETTE (for herself and Mr. DOGGETT) 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 the protection of human subjects in research.

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 “Protection for Partici-
5 pants in Research Act of 2008”.

1 **SEC. 2. PROTECTION OF HUMAN SUBJECTS IN RESEARCH;**
2 **UNIFORM NATIONAL APPLICABILITY OF COM-**
3 **MON RULE AND PROVISIONS PROTECTING**
4 **VULNERABLE POPULATIONS.**

5 Part H of title IV of the Public Health Service Act
6 (42 U.S.C. 289 et seq.) is amended by inserting after sec-
7 tion 491 the following section:

8 **“SEC. 491A. PROTECTION OF HUMAN SUBJECTS; UNIFORM**
9 **NATIONAL APPLICABILITY OF COMMON RULE**
10 **AND PROVISIONS PROTECTING VULNERABLE**
11 **POPULATIONS.**

12 **“(a) PROTECTION OF HUMAN SUBJECTS.—**

13 **“(1) IN GENERAL.—**Except as provided in para-
14 graph (2), all human subject research shall be con-
15 ducted in accordance with the Common Rule, and as
16 applicable to the human subjects involved in such re-
17 search, with the vulnerable-populations rules.

18 **“(2) FDA RESEARCH.—**

19 **“(A) APPLICABLE RULES.—**All human
20 subject research that is subject to the Federal
21 Food, Drug, and Cosmetic Act or to section
22 351 of this Act shall be conducted—

23 **“(i) in accordance with the provisions**
24 **of parts 50 and 56 of title 21, Code of**
25 **Federal Regulations (or any successor reg-**
26 **ulations); and**

1 “(ii) as applicable to the human sub-
2 jects involved in such research, in accord-
3 ance with provisions applicable to vulner-
4 able populations under part 56 of such
5 title 21 (or any successor regulations) and
6 subpart D of part 50 of such title 21 (or
7 any successor regulations).

8 “(B) REFERENCES.—In the case of human
9 subject research described in subparagraph
10 (A)—

11 “(i) each reference in this section or
12 section 491B to the Common Rule shall be
13 treated as a reference to the provisions de-
14 scribed in subparagraph (A)(i); and

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

19 “(3) APPLICABILITY.—Paragraphs (1) and (2)
20 apply to human subject research that—

21 “(A) is conducted, supported, or otherwise
22 subject to regulation under a provision of Fed-
23 eral law (other than this section), without re-
24 gard to whether the Federal agency that admin-
25 isters such law has taken administrative action

1 to make the Common Rule applicable to the
2 agency; or

3 “(B) is not described in subparagraph (A)
4 and has activities that are in or that affect
5 interstate commerce.

6 “(4) HARMONIZATION.—

7 “(A) REVIEW OF REGULATIONS.—Not
8 later than 18 months after the date of the en-
9 actment of the Protection for Participants in
10 Research Act of 2008, the Secretary shall com-
11 plete a review of the provisions of subpart A of
12 part 46 of title 45, Code of Federal Regulations
13 (referred to in this paragraph as ‘title 45 regu-
14 lations’), and the provisions of parts 50 and 56
15 of title 21, Code of Federal Regulations (re-
16 ferred to in this paragraph as ‘title 21 regula-
17 tions’), in order to determine to what extent the
18 differences in approach between the title 45
19 regulations and the title 21 regulations can be
20 harmonized toward the goal of having only such
21 differences as are appropriate to reflect the
22 legal or factual variations in human subject re-
23 search described in paragraph (2)(A) relative to
24 other human subject research. The areas of dif-
25 ference reviewed shall include (but are not lim-

1 ited to) differences regarding the existence of a
2 significant financial interest; provisions for re-
3 search relating to emergency interventions; the
4 definition of ‘institution’; and requirements for
5 attestations by investigators regarding the pro-
6 tection of human subjects.

7 “(B) RULEMAKING.—

8 “(i) PURSUANT TO HARMONIZATION
9 REVIEW.—Not later than three years after
10 completing the review under subparagraph
11 (A), the Secretary shall publish in the Fed-
12 eral Register a proposed rule to modify the
13 title 45 regulations, or the title 21 regula-
14 tions, or both, in accordance with the find-
15 ings of the review, unless the review finds
16 that removing any of the differences in ap-
17 proach between the title 45 regulations and
18 the title 21 regulations is not practicable.

19 “(ii) SUBSEQUENT RULEMAKING.—
20 After the expiration of the three-year pe-
21 riod referred to in clause (i), or the publi-
22 cation of the proposed rule under clause
23 (i), whichever occurs first, any rule pro-
24 mulgated by the Secretary that modifies
25 the title 45 regulations or the title 21 reg-

1 ulations (including a modification that
2 adds provisions), and results in there being
3 a difference between the title 45 regula-
4 tions and the title 21 regulations, shall be
5 accompanied in the Federal Register by a
6 statement of the reasons underlying the
7 determination of the Secretary that, with
8 respect to the goal described in subpara-
9 graph (A), the difference is appropriate to
10 reflect the legal or factual variations in
11 human subject research described in para-
12 graph (2)(A) relative to other human sub-
13 ject research.

14 “(b) COMMON RULE; OTHER DEFINITIONS.—

15 “(1) COMMON RULE; VULNERABLE-POPULATION
16 RULES.—For purposes of this section:

17 “(A) The term ‘Common Rule’ means the
18 provisions of subpart A of part 46 of title 45,
19 Code of Federal Regulations (or any successor
20 regulations).

21 “(B) The term ‘vulnerable-population
22 rules’ means the provisions of subparts B
23 through D of such part 46 (or any successor
24 regulations).

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

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

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

17 “(4) OTHER DEFINITIONS.—For purposes of
18 this section:

19 “(A) The term ‘classified’, with respect to
20 human subject research, refers to research that,
21 within the meaning of section 552(b)(1)(A) of
22 title 5, United States Code, is—

23 “(i) specifically authorized under cri-
24 teria established by an Executive order to

1 be kept secret in the interest of national
2 defense or foreign policy; and

3 “(ii) is in fact properly classified pur-
4 suant to such Executive order.

5 “(B) The term ‘data safety and monitoring
6 committee’, with respect to a human subject re-
7 search project, means a group of individuals
8 with appropriate expertise that, on an ongoing
9 basis during the conduct of such research
10 project—

11 “(i) reviews data that is generated
12 during the project;

13 “(ii) advises the investigator and
14 sponsor regarding the continuing safety of
15 human subjects who are or will be partici-
16 pating in the project; and

17 “(iii) advises such investigator and
18 sponsor on the continued validity and sci-
19 entific merit of the project.

20 “(C) The term ‘Federal agency’ has the
21 meaning given the term ‘Executive agency’ in
22 section 105 of title 5, United States Code.

23 “(D) The terms ‘institution served by an
24 Institutional Review Board’ and ‘institution
25 served by the Board’ mean the public or private

1 entity (university, health care provider, health
2 plan, research organization, government agency,
3 independent institutional review board, or other
4 entity) that establishes and is responsible for
5 the operation of the Institutional Review Board.

6 “(E) The term ‘Institutional Review
7 Board’ has the meaning that applies under the
8 Common Rule.

9 “(F) The term ‘lead Institutional Review
10 Board’ means an Institutional Review Board
11 that otherwise meets the requirements of the
12 Common Rule and enters into a written agree-
13 ment with an institution, another Institutional
14 Review Board, a sponsor, or a principal investi-
15 gator to approve and oversee human subject re-
16 search that is conducted at multiple locations.
17 For purposes of this section, references to an
18 Institutional Review Board include an Institu-
19 tional Review Board that serves a single institu-
20 tion as well as a lead Institutional Review
21 Board.

22 “(G) The term ‘principal investigator’,
23 with respect to human subject research, means
24 the individual who, at the research location in-

1 involved, has the principal responsibility for the
2 conduct of the research.

3 “(H)(i) Except as provided in clause (ii),
4 the term ‘sponsor’, with respect to human sub-
5 ject research, means the entity that has the
6 principal financial responsibility for the conduct
7 of the research.

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

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

15 “(1) IN GENERAL.—The Common Rule (includ-
16 ing provisions regarding exemptions) and the vulner-
17 able-populations rules, as in effect on the day before
18 the date of the enactment of the Protection for Par-
19 ticipants in Research Act of 2008, continue to be in
20 effect on and after such date, subject to paragraph
21 (2).

22 “(2) MODIFICATIONS.—

23 “(A) COMPLIANCE WITH LAW.—Promptly
24 after the date of the enactment of the Act re-
25 ferred to in paragraph (1), the Secretary shall

1 promulgate regulations to make such modifica-
2 tions to the provisions of the Common Rule as
3 may be necessary to ensure that such provisions
4 implement, and do not conflict with, this sec-
5 tion.

6 “(B) OTHER MODIFICATIONS.—This sec-
7 tion may not be construed as affecting the au-
8 thority of the Secretary to modify the provisions
9 of the Common Rule or the vulnerable-popu-
10 lations rules, except to the extent that any such
11 modification is in conflict with this section. Any
12 such modification shall be made by regulation.

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

15 “(i) IN GENERAL.—The Secretary
16 shall, with respect to the Common Rule,
17 consider the matters specified in clause
18 (iii) and make a determination of whether
19 any of the provisions of such Rule should
20 be modified accordingly.

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

1 “(I) except as provided in sub-
2 clause (II), not later than 18 months
3 after the date of the enactment of the
4 Protection for Participants in Re-
5 search Act of 2008; and

6 “(II) in the case of a determina-
7 tion on the matters specified in clause
8 (iii)(VII), not later than 18 months
9 after the submission of the report re-
10 quired by section 7 of the Protection
11 for Participants in Research Act of
12 2008.

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

17 “(I) Whether the list of exemp-
18 tions from applicability of the Com-
19 mon Rule, as in effect on the day be-
20 fore the date of enactment referred to
21 in clause (ii)(I), should be modified or
22 new categories of exemptions estab-
23 lished.

24 “(II) Whether and under what
25 circumstances research that studies

1 human tissue or other types of clinical
2 specimens should not be considered
3 human subject research.

4 “(III) Whether and under what
5 circumstances research that studies
6 data that do not involve any inter-
7 action or intervention with a living
8 human should be considered human
9 subject research.

10 “(IV) Whether the list of cat-
11 egories of research that are exempt
12 from Investigational Review Board re-
13 view or are eligible for expedited re-
14 view under the Common Rule, as in
15 effect on the day before the date of
16 enactment referred to in clause (i),
17 should be modified, and whether new
18 categories of such exempt research or
19 research eligible for expedited review
20 should be established.

21 “(V) Whether modified proce-
22 dures should apply to human subject
23 research that poses minimal risk to
24 the subjects, including whether there
25 are any types of such research for

1 which some aspect of the requirement
2 of informed consent or documentation
3 of informed consent should apply dif-
4 ferently.

5 “(VI) Whether Institutional Re-
6 view Boards include sufficient num-
7 bers of minority individuals (as de-
8 fined in section 485E(c)) as Board
9 members when reviewing proposals
10 designed to have a population of
11 human subjects a majority of whom
12 are minority individuals.

13 “(VII) Whether the requirements
14 for the number of members of an In-
15 stitutional Review Board who are in-
16 dividuals whose primary expertise is
17 in nonscientific areas, and the number
18 of members of an Institutional Review
19 Board who are individuals who are
20 not affiliated with the institution
21 served by the Board, should be in-
22 creased.

23 “(VIII) Such additional matters
24 as the Secretary determines to be ap-
25 propriate.

1 “(D) AGENCY-SPECIFIC ADDITIONAL PRO-
2 TECTIONS.—With respect to human subject re-
3 search that is conducted, supported, or other-
4 wise subject to regulation under a provision of
5 Federal law (other than this section), the Sec-
6 retary may under subparagraph (A) permit the
7 Federal agency involved to establish additional
8 protections for the protection of human subjects
9 if the Secretary determines that such additional
10 protections are not in conflict with protections
11 established under this section.

12 “(d) RIGHT OF INFORMED CONSENT.—

13 “(1) IN GENERAL.—For purposes of subsection
14 (a), a principal investigator may not, except as pro-
15 vided in the Common Rule, involve an individual as
16 a subject in human subject research unless the in-
17 vestigator or other knowledgeable person has ob-
18 tained the informed consent of the individual to be
19 a subject.

20 “(2) LEGALLY AUTHORIZED REPRESENTA-
21 TIVE.—References in this section to obtaining con-
22 sent from an individual shall be considered to be ref-
23 erences to obtaining consent from the legally author-
24 ized representative of the individual in any case in

1 which the individual lacks legal competence to pro-
2 vide consent.

3 “(3) CERTAIN REQUIREMENTS REGARDING DIS-
4 CLOSURE AND UNDERSTANDING.—The Secretary
5 shall establish criteria regarding consent under para-
6 graph (1) that—

7 “(A) provide for the provision of full and
8 complete information relevant to the research to
9 a prospective human subject;

10 “(B) require such information to be pro-
11 vided in language understandable to such sub-
12 ject;

13 “(C) require that only individuals knowl-
14 edgeable about the research provide such infor-
15 mation to the subject and answer questions
16 from the subject; and

17 “(D) require that information be provided
18 to the subject on how to contact the Office for
19 Human Research Protections to submit ques-
20 tions about the rights of subjects or to report
21 concerns regarding the research.

22 “(4) WRITTEN ATTESTATION BY INVESTI-
23 GATOR.—A principal investigator who involves a
24 human subject in research shall, in accordance with
25 the criteria of the Secretary, file with the Institu-

1 tional Review Board for the research a written attes-
2 tation that the investigator is familiar with require-
3 ments for the protection of human subjects, includ-
4 ing the requirement of informed consent, and agrees
5 to comply with such requirements.

6 “(e) INSTITUTIONAL REVIEW BOARDS.—

7 “(1) REQUIREMENTS FOR BOARDS.—Human
8 subject research may not be conducted unless an In-
9 stitutional Review Board has, for purposes of the
10 Common Rule (and the vulnerable-populations rules,
11 as applicable), approved the proposal for such re-
12 search. With respect to the research involved, the
13 approval by the Board of the proposal for the re-
14 search is not effective unless, in addition to condi-
15 tions established by the Secretary, the following con-
16 ditions are met:

17 “(A) The institution served by the Board
18 ensures that the Board has an orientation pro-
19 gram for new members and a continuing edu-
20 cation program for existing members of the
21 Board, and with respect to ethical matters that
22 relate to research, a continuing education pro-
23 gram for all members of the Board.

24 “(B) The institution served by the Board
25 has submitted to the Secretary a registration

1 informing the Secretary of the existence of the
2 Board, and the registration was in such form,
3 was made in such manner, and contained such
4 information as the Secretary requested regard-
5 ing functions of the Board under this section.

6 “(C) In the case of a proposal for a re-
7 search project requiring a data safety and mon-
8 itoring plan, the Board reviews the data safety
9 and monitoring plan (pursuant to subsection
10 (f)) as a part of the review by the Board of the
11 proposal.

12 “(D) With respect to the research involved,
13 each member of the Board has disclosed any
14 significant financial interest, as defined by ap-
15 plicable Federal regulations, to the institution
16 served by the Board, and such institution has
17 disclosed any such disclosures to the Board.

18 “(E) A member of the Board does not par-
19 ticipate in the review by the Board of a pro-
20 posal for research if the member has a signifi-
21 cant financial interest, as defined by applicable
22 Federal regulations, in the research. The provi-
23 sion by such member of information to other
24 members of the Board does not constitute

1 Board participation for purposes of this sub-
2 paragraph.

3 “(F) The institution served by the Board
4 annually submits to the Secretary a report that
5 compiles data on the number of new research
6 proposals reviewed, the number of continuing
7 research projects reviewed, the number of re-
8 viewed biomedical research proposals, the num-
9 ber of reviewed behavioral or social sciences re-
10 search proposals, the number of reviewed multi-
11 disciplinary research proposals, and any addi-
12 tional information determined appropriate by
13 the Secretary.

14 “(G) The institution served by the Board
15 submits to the Secretary such reports regarding
16 the Board as the Secretary determines to be ap-
17 propriate.

18 “(2) NOTIFICATION OF INSTITUTIONAL REVIEW
19 BOARD AND SPONSORS BY INVESTIGATORS.—

20 “(A) In submitting to an Institutional Re-
21 view Board a proposal for human subject re-
22 search, the investigators for the research shall
23 notify the institution served by the Board—

1 “(i) of any significant financial inter-
2 est, as defined by applicable Federal regu-
3 lations;

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

14 “(iii) whether the proposal has been
15 submitted to any other Institutional Re-
16 view Board and, as applicable, of any find-
17 ings made by such Board.

18 “(B) A notification required by subpara-
19 graph (A) shall be submitted to the institution
20 served by the Board—

21 “(i) at the time of submitting the pro-
22 posal for human subject research to the
23 Board; or

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

1 “(3) INSTITUTION REVIEW OF CONFLICTS OF
2 INTEREST.—The institution served by an Institu-
3 tional Review Board shall review such significant fi-
4 nancial interests as are submitted under paragraph
5 (2) to determine whether such interests create or
6 may reasonably appear to create conflicts of interest,
7 and then shall seek to manage, reduce, or eliminate
8 such conflicts of interest.

9 “(4) PROJECTS INVOLVING MULTIPLE LOCA-
10 TIONS.—For purposes of meeting the Common Rule
11 requirements for review and supervision of research
12 by an Institutional Review Board, such activities
13 may be performed by an Institutional Review Board
14 or a lead Institutional Review Board, at the option
15 of the institution where the research is conducted.

16 “(5) VOLUNTARY ACCREDITATION.—The Sec-
17 retary may in accordance with this paragraph facili-
18 tate the accreditation of institutions and Institu-
19 tional Review Boards by recognizing a private ac-
20 crediting entity or entities. For purposes of the pre-
21 ceding sentence:

22 “(A) The Secretary may recognize an ac-
23 crediting entity if—

24 “(i) such entity submits to the Sec-
25 retary the standards and procedures that

1 the entity requires institutions and Institu-
2 tional Review Boards to meet in order to
3 be accredited by the entity;

4 “(ii) the Secretary determines that
5 such standards and procedures include
6 standards and procedures ensuring that
7 the policies and procedures of institutions
8 and Institutional Review Boards accredited
9 by the entity are in compliance with Fed-
10 eral regulations governing human subject
11 research; and

12 “(iii) the entity annually submits to
13 the Secretary a report describing any
14 changes in the standards and procedures
15 described in clause (ii).

16 “(B) The Secretary may not require that
17 any institution, Institutional Review Board, or
18 program for the protection of human subjects
19 in research, or any component thereof, be ac-
20 credited.

21 “(C) Nothing in this section may be con-
22 strued as authorizing the Secretary—

23 “(i) to establish or approve accredita-
24 tion standards or procedures for institu-
25 tions, Institutional Review Boards, or pro-

1 grams for the protection of human subjects
2 in research, or any component thereof; or
3 “(ii) to recognize any standards or
4 procedures for institutions or Institutional
5 Review Boards other than the standards
6 and procedures described in subparagraph
7 (A)(ii).

8 “(6) COST RECOVERY.—Institutions may re-
9 cover costs associated with compliance for human
10 subject protections under this part from government
11 sponsors of research as direct costs.

12 “(f) IMPROVED MONITORING OF RESEARCH
13 RISKS.—With respect to high-risk human subject research
14 projects:

15 “(1) The Secretary shall establish criteria for
16 identifying proposals for such projects that require
17 a data safety and monitoring plan. The criteria shall
18 include—

19 “(A) a provision that the Secretary may
20 require the sponsor of the project to utilize a
21 data safety and monitoring committee in affili-
22 ation with the research project;

23 “(B) minimum requirements for the re-
24 porting by the principal investigator of informa-
25 tion on such plan to the Institutional Review

1 Board for the research project and to the insti-
2 tution served by the Board; and

3 “(C) the requirement that such committee
4 provide reports on the findings of the com-
5 mittee regarding the research project to such
6 investigator, Board, and institution.

7 “(2)(A) The Secretary shall require the prin-
8 cipal investigator to report to the Institutional Re-
9 view Board for the research project and the sponsor
10 of the research project—

11 “(i) in the case of any unanticipated
12 problem in the research project involving
13 risks to human subjects or other individ-
14 uals, immediately; and

15 “(ii) in the case of any adverse event
16 in the research project, in a timely manner
17 appropriate to the severity of the event and
18 whether the event is unexpected.

19 “(B) An unanticipated problem or adverse
20 event referred to in clause (i) or (ii) of subparagraph
21 (A), respectively, shall be reported by the principal
22 investigator, in addition to the reports required by
23 subparagraph (A), as directed by the Secretary by
24 regulation. Such regulations shall ensure comprehen-
25 sive and coordinated reporting to all relevant parties.

1 “(g) INSTITUTIONAL PROGRAMS OF EDUCATION.—
2 For fiscal year 2009 and subsequent fiscal years, the Sec-
3 retary may not make an award of a grant, cooperative
4 agreement, or contract under this Act to a public entity
5 or a private academic institution, or make an award of
6 a grant, cooperative agreement, or contract under this Act
7 for the conduct of research at or through or in affiliation
8 with a public entity or a private academic institution, un-
9 less the public entity or private academic institution (as
10 the case may be) maintains or contracts for a comprehen-
11 sive and ongoing program to educate investigators and
12 Board members on the protection of human subjects in
13 research.

14 “(h) CERTAIN CLASSIFIED HUMAN SUBJECT RE-
15 SEARCH.—Notwithstanding any other provision of law,
16 Federal funds may not be expended for the conduct of
17 classified human subject research if—

18 “(1) the Institutional Review Board reviewing
19 the proposal for the research pursuant to this sec-
20 tion has under the Common Rule waived the re-
21 quirement to obtain the informed consent of the
22 human subjects in the research; or

23 “(2) the research is exempt from the require-
24 ment under the Common Rule that the proposal for
25 the research be reviewed by such a Board.

1 “(i) DISCLOSURE OF VIOLATIONS.—

2 “(1) DISCLOSURES.—Upon the request of an
3 Institutional Review Board, the Secretary shall de-
4 termine whether an entity (including an individual,
5 as applicable under the request) has violated any re-
6 quirement under this section, and shall disclose to
7 such Board the findings of the Secretary.

8 “(2) NOTICE TO SUBJECT OF DISCLOSURE.—If
9 pursuant to a request under paragraph (1) the Sec-
10 retary discloses that an entity has violated a require-
11 ment under this section, the Secretary shall in writ-
12 ing notify the entity of the disclosure, including the
13 identity of the Institutional Review Board to which
14 the disclosure was made.

15 “(j) APPLICABILITY OF REQUIREMENTS.—The re-
16 quirements of this section apply on and after the date of
17 the enactment of the Protection for Participants in Re-
18 search Act of 2008.”.

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

20 Part H of title IV of the Public Health Service Act
21 (42 U.S.C. 289 et seq.), as amended by section 2 of this
22 Act, is amended by inserting after section 491A the fol-
23 lowing section:

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

2 “(a) IN GENERAL.—There is established within the
3 office of the Secretary an office to be known as the Office
4 for Human Research Protections (in this section referred
5 to as the ‘Office’). The Office shall be headed by a direc-
6 tor, who shall be appointed by the Secretary. The Sec-
7 retary shall carry out this section acting through the Di-
8 rector of the Office.

9 “(b) CERTAIN DUTIES.—The Director of the Of-
10 fice—

11 “(1) shall provide for the protection of human
12 subjects in research by carrying out activities in ac-
13 cordance with subsection (d) regarding compliance
14 with the Common Rule, as defined in and modified
15 pursuant to section 491A;

16 “(2) shall establish criteria regarding assur-
17 ances of compliance with the requirements of the
18 Common Rule;

19 “(3) shall direct activities within the Depart-
20 ment of Health and Human Services, and coordinate
21 the activities of the Department with other Federal
22 departments and agencies, with respect to the pro-
23 tection of subjects in human subject research;

24 “(4) may, in collaboration with the Director of
25 NIH, the Commissioner of Food and Drugs, or the
26 head of any other Federal department or agency,

1 carry out educational and quality improvement pro-
2 grams for human subject protections for principal
3 investigators, members of Institutional Review
4 Boards, and other appropriate persons, including the
5 generation of resource materials relating to the re-
6 sponsibilities of the research community for the pro-
7 tection of human subjects in research;

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

10 “(A) consult with the entity regarding im-
11 provements in human subject protections in
12 such research; and

13 “(B) provide advice on compliance with the
14 Common Rule, including with respect to dif-
15 fering interpretations among Institutional Re-
16 view Boards of a provision of such Rule;

17 “(6) may make grants to entities that conduct
18 or support human subject research for the purpose
19 of assisting the entities in carrying out programs to
20 recruit and train minority individuals (as defined in
21 section 485E(c)) to serve as members of Institu-
22 tional Review Boards;

23 “(7) shall consult with experts in biomedical,
24 behavioral, and social sciences research in carrying
25 out the duties of the Director; and

1 “(8) shall carry out such additional authorities
2 of the Secretary regarding the protection of human
3 subjects in research as the Secretary determines to
4 be appropriate.

5 “(c) MODEL EDUCATION PROGRAM.—The Director
6 of the Office may make grants for the development of a
7 model education program to be used by institutions served
8 by Institutional Review Boards to satisfy the requirements
9 under section 491A(e)(1)(A) and to develop best practices
10 in institutional management of human subject research.

11 “(d) COMPLIANCE AND ENFORCEMENT.—

12 “(1) AUDITS OF INVESTIGATORS AND INSTITU-
13 TIONS.—The Director of the Office may conduct au-
14 dits of entities that conduct or support human sub-
15 ject research in order to determine whether such en-
16 tities are complying with the Common Rule.

17 “(2) CORRECTIVE ACTION PLAN.—If the Direc-
18 tor of the Office determines that an entity referred
19 to in paragraph (1) is not in compliance with the
20 Common Rule, the Director of the Office, after pro-
21 viding to an appropriate representative of the entity
22 an oral or written summary of the reasons under-
23 lying such determination, may require the entity to
24 develop and to implement a plan for corrective ac-
25 tion to bring the entity into compliance.

1 “(3) RESTRICTIONS.—If the Director of the Of-
2 fice determines that an entity referred to in para-
3 graph (1) is not in compliance with the Common
4 Rule, the Director may impose restrictions on the
5 extent to which the entity may conduct or support
6 human subject research. The restrictions may in-
7 clude any of the following:

8 “(A) Suspending research protocols.

9 “(B) Prohibiting the inclusion of additional
10 human subjects in particular research projects.

11 “(C) Suspending or terminating particular
12 research projects, unless doing so would endan-
13 ger the human subjects participating in such
14 projects.

15 “(D) Suspending the provision of Federal
16 funds for particular research projects conducted
17 or supported by or through the entity, or for
18 particular research protocols of the entity.

19 “(E) Suspending the provision of Federal
20 funds for all research projects conducted or
21 supported by or through the entity, in any case
22 in which the Secretary determines that the non-
23 compliance creates a significant threat to the
24 rights and welfare of human subjects in such
25 projects.

1 “(F) In the case of individuals who are or
2 were investigators in the research involved,
3 after notice and an opportunity for a hearing—

4 “(i) suspending or debarring the indi-
5 viduals from receiving Federal funds for
6 conducting human subject research; or

7 “(ii) suspending or debarring the indi-
8 viduals from serving as principal investiga-
9 tors in human subject research.

10 “(4) INSTITUTIONAL REVIEW BOARDS.—

11 “(A) AUDITS.—In carrying out paragraph
12 (1), the Director of the Office may conduct au-
13 dits of Institutional Review Boards in order to
14 determine whether such Boards are complying
15 with the Common Rule (including conditions
16 described in section 491A(e)).

17 “(B) CORRECTIVE ACTION PLAN.—If the
18 Director of the Office determines that an Insti-
19 tutional Review Board is not in compliance with
20 the Common Rule, the Director of the Office,
21 after providing to an appropriate representative
22 of such Board, or of the institution served by
23 the Board, an oral or written summary of the
24 reasons underlying such determination, may re-
25 quire the Board to develop and to implement a

1 plan for corrective action to bring the Board
2 into compliance.

3 “(C) RESTRICTIONS.—

4 “(i) IN GENERAL.—If the Director de-
5 termines that an Institutional Review
6 Board is not in compliance with the Com-
7 mon Rule, the Director may—

8 “(I) in the case of the research
9 projects with respect to which the
10 Board was or is not in compliance,
11 provide that the approvals of the
12 Board for such projects are not effec-
13 tive for purposes of section
14 491A(e)(1), unless such projects were
15 approved by another Institutional Re-
16 view Board; or

17 “(II) provide that all approvals of
18 research by the Board are not effec-
19 tive for purposes of such section, in
20 any case in which the Director deter-
21 mines that the noncompliance creates
22 a significant threat to the rights and
23 welfare of human subjects in projects
24 approved by the Board.

1 “(ii) RESULTING RISKS.—In deter-
2 mining that an approval is not effective
3 under subclause (I) or (II) of clause (i),
4 the Director shall take into consideration
5 human subject safety risks that may result
6 from such a determination, including the
7 immediate withdrawal of a study treat-
8 ment, and shall require that appropriate
9 measures be taken to eliminate such risks.

10 “(D) PROJECTS INVOLVING MULTIPLE LO-
11 CATIONS.—In the case of a project of human
12 subject research for which there is an agree-
13 ment described in section 491A(b)(4)(F) (relat-
14 ing to multiple Institutional Review Boards),
15 the Director of the Office shall, in carrying out
16 authorities under this subsection with respect to
17 an Institutional Review Board, ensure that no
18 action is taken that adversely affects the oper-
19 ation of a project of human subject research at
20 any project location for which such Institutional
21 Review Board had no responsibilities.

22 “(5) NOTIFICATION OF FEDERAL AND STATE
23 REGULATORY AGENCIES.—In any case in which the
24 Director of the Office takes an action described in
25 paragraph (3)(E) or (4)(C)(ii) against an entity that

1 conducts or supports human subject research, or
2 against an Institutional Review Board, respectively,
3 the Director shall notify relevant Federal and State
4 regulatory agencies, and as applicable, the sponsors
5 of the research, of the deficiencies in the operation
6 of the entity or Board.

7 “(6) COORDINATION WITH FOOD AND DRUG AD-
8 MINISTRATION.—In the case of human subject re-
9 search that is subject to the Federal Food, Drug,
10 and Cosmetic Act or to section 351 of this Act, no
11 authority under this subsection may be carried out
12 with respect to an entity that conducts or supports
13 such research, or with respect to an Institutional Re-
14 view Board, unless the Commissioner of Food and
15 Drugs concurs in the exercise of the authority in-
16 volved.

17 “(e) FUNDING.—

18 “(1) AUTHORIZATION OF APPROPRIATIONS.—
19 For the purpose of carrying out this section, there
20 are authorized to be appropriated \$20,000,000 for
21 fiscal year 2009, and such sums as may be nec-
22 essary for fiscal year 2010 and each subsequent fis-
23 cal year.

24 “(2) MODEL EDUCATION PROGRAM.—For the
25 purpose of carrying out subsection (c), there are au-

1 thorized to be appropriated such sums as may be
2 necessary for fiscal year 2009 and each subsequent
3 fiscal year.

4 “(3) RULE OF CONSTRUCTION.—Nothing in
5 this section or section 491A may be construed as a
6 change in the budget authority or authorization of
7 appropriations for the Food and Drug Administra-
8 tion.”.

9 **SEC. 4. AMENDMENTS REGARDING PROCESS FOR RE-**
10 **SPONDING TO REPORTS OF VIOLATIONS.**

11 Section 491(b)(2) of the Public Health Service Act
12 (42 U.S.C. 289(b)(2)) is amended—

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

16 (2) in the second sentence, by inserting after
17 “this Act” the following: “, the sharing of informa-
18 tion between the Director of NIH and the Director
19 of such Office, and”.

20 **SEC. 5. ENHANCED HUMAN SUBJECT PROTECTIONS FOR**
21 **PEOPLE WITH DIMINISHED DECISIONMAKING**
22 **CAPACITY.**

23 Not later than three years after the date of the enact-
24 ment of this Act, the Secretary of Health and Human
25 Services shall, for purposes of section 491A of the Public

1 Health Service Act, promulgate regulations to enhance the
2 protection of people with diminished decisionmaking ca-
3 pacity with respect to their participation as subjects in
4 human subject research.

5 **SEC. 6. RULE OF CONSTRUCTION REGARDING INDIVIDUAL**
6 **AGENCY OFFICES.**

7 The amendments made by this Act may not be con-
8 strued as terminating any office or other administrative
9 unit in a Federal agency that, on the day before the date
10 of the enactment of this Act, had duties relating to the
11 protection of human subjects in research conducted, sup-
12 ported, or otherwise subject to regulation under Federal
13 law.

14 **SEC. 7. STUDY ON INCREASING THE NUMBER OF CERTAIN**
15 **IRB MEMBERS.**

16 (a) STUDY.—Not later than 36 months after the date
17 of the enactment of this Act, the Secretary of Health and
18 Human Services shall—

19 (1) complete a study on whether the require-
20 ments for the number of members of an Institu-
21 tional Review Board who are individuals whose pri-
22 mary expertise is in nonscientific areas, and the
23 number of members of an Institutional Review
24 Board who are individuals who are not affiliated

1 with the institution served by the Board, should be
2 increased; and

3 (2) submit a report to the Congress on the re-
4 sults of such study.

5 (b) DEFINITIONS.—In this section, the terms “insti-
6 tution served by the Board” and “Institutional Review
7 Board” have the meanings given to such terms in section
8 491A(b)(4) of the Public Health Service Act, as added by
9 section 2 of this Act.

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