

109TH CONGRESS
2^D SESSION

H. R. 5578

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

IN THE HOUSE OF REPRESENTATIVES

JUNE 9, 2006

Ms. DEGETTE (for herself and Mr. GILLMOR) 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 2006”.

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.—All human subject research
14 shall be conducted in accordance with the Common
15 Rule, and as applicable to the human subjects in-
16 volved in such research, with the vulnerable-popu-
17 lations rules.

18 “(2) APPLICABILITY.—Paragraph (1) applies to
19 human subject research that—

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

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

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

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

7 “(A) Except as provided in subparagraph
8 (B):

9 “(i) The term ‘Common Rule’ means
10 the provisions of subpart A of part 46 of
11 title 45, Code of Federal Regulations (or
12 any successor regulations), subject to sub-
13 paragraph (C).

14 “(ii) The term ‘vulnerable-population
15 rules’ means the provisions of subparts B
16 through D of such part 46 (or any suc-
17 cessor regulations), subject to subpara-
18 graph (C).

19 “(B) In the case of human subject re-
20 search that is subject to the Federal Food,
21 Drug, and Cosmetic Act or to section 351 of
22 this Act:

23 “(i) The term ‘Common Rule’ means
24 the provisions of parts 50 and 56 of title

1 21, Code of Federal Regulations (or any
2 successor regulations).

3 “(ii) The term ‘vulnerable-population
4 rules’ has the meaning applicable under
5 part 56 of such title 21 (or any successor
6 regulations), and includes the provisions of
7 subpart D of part 50 of such title 21 (or
8 any successor regulations).

9 “(C) In the case of human subject research
10 to which both subparagraphs (A) and (B)
11 apply, the terms ‘Common Rule’ and ‘vulner-
12 able-population rules’ have the meaning given
13 such terms in subparagraph (B).

14 “(2) HARMONIZATION.—

15 “(A) REVIEW OF REGULATIONS.—Not
16 later than 18 months after the date of the en-
17 actment of the Protection for Participants in
18 Research Act of 2006, the Secretary shall com-
19 plete a review of the provisions of subpart A of
20 part 46 of title 45, Code of Federal Regulations
21 (referred to in this paragraph as ‘title 45 regu-
22 lations’), and the provisions of parts 50 and 56
23 of title 21, Code of Federal Regulations (re-
24 ferred to in this paragraph as ‘title 21 regula-
25 tions’), in order to determine to what extent the

1 differences in approach between the title 45
2 regulations and the title 21 regulations can be
3 harmonized toward the goal of having only such
4 differences as are appropriate to reflect the
5 legal or factual variations in human subject re-
6 search described in paragraph (1)(B) relative to
7 other human subject research. The areas of dif-
8 ference reviewed shall include (but are not lim-
9 ited to) differences regarding the existence of a
10 significant financial interest; provisions for re-
11 search relating to emergency interventions; the
12 definition of ‘institution’; and requirements for
13 attestations by clinical investigators regarding
14 the protection of human subjects.

15 “(B) RULEMAKING.—

16 “(i) PURSUANT TO HARMONIZATION
17 REVIEW.—Not later than three years after
18 completing the review under subparagraph
19 (A), the Secretary shall publish in the Fed-
20 eral Register a proposed rule to modify the
21 title 45 regulations, or the title 21 regula-
22 tions, or both, in accordance with the find-
23 ings of the review, unless the review finds
24 that removing any of the differences in ap-

1 proach between the title 45 regulations and
2 the title 21 regulations is not practicable.

3 “(ii) SUBSEQUENT RULEMAKING.—

4 After the expiration of the three-year pe-
5 riod referred to in clause (i), or the publi-
6 cation of the proposed rule under clause
7 (i), whichever occurs first, any rule pro-
8 mulgated by the Secretary that modifies
9 the title 45 regulations or the title 21 reg-
10 ulations (including a modification that
11 adds provisions), and results in there being
12 a difference between the title 45 regula-
13 tions and the title 21 regulations, shall be
14 accompanied in the Federal Register by a
15 statement of the reasons underlying the
16 determination of the Secretary that, with
17 respect to the goal described in subpara-
18 graph (A), the difference is appropriate to
19 reflect the legal or factual variations in
20 human subject research described in para-
21 graph (1)(B) relative to other human sub-
22 ject research.

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

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

8 “(B) 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 ‘human subject’ has the
12 meaning given such term in such part 50, and
13 the term ‘human subject research’ means a clin-
14 ical investigation as defined in such part 50.

15 “(4) OTHER DEFINITIONS.—For purposes of
16 this section:

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

21 “(i) specifically authorized under cri-
22 teria established by an Executive order to
23 be kept secret in the interest of national
24 defense or foreign policy; and

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

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

9 “(i) reviews data that is generated
10 during the project;

11 “(ii) advises the sponsor regarding the
12 continuing safety of human subjects who
13 are or will be participating in the project;
14 and

15 “(iii) advises such sponsor on the con-
16 tinued validity and scientific merit of the
17 project.

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

21 “(D) The term ‘institution served by an
22 Institutional Review Board’ means the public or
23 private entity (university, health care provider,
24 health plan, research organization, government
25 agency, or other entity) that establishes and is

1 responsible for the operation of the Institutional
2 Review Board.

3 “(E) The term ‘Institutional Review
4 Board’ has the meaning that applies under the
5 Common Rule.

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

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

24 “(H)(i) Except as provided in clause (ii),
25 the term ‘sponsor’, with respect to human sub-

1 ject research, means the entity that has the
2 principal financial responsibility for the conduct
3 of the research.

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

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

11 “(1) IN GENERAL.—The Common Rule (includ-
12 ing provisions regarding exemptions) and the vulner-
13 able-populations rules, as in effect on the day before
14 the date of the enactment of the Protection for Par-
15 ticipants in Research Act of 2006, continue to be in
16 effect on and after such date, subject to paragraph
17 (2).

18 “(2) MODIFICATIONS.—

19 “(A) COMPLIANCE WITH LAW.—Promptly
20 after the date of the enactment of the Act re-
21 ferred to in paragraph (1), the Secretary shall
22 promulgate regulations to make such modifica-
23 tions to the provisions of the Common Rule as
24 may be necessary to ensure that such provisions

1 implement, and do not conflict with, this sec-
2 tion.

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

10 “(C) CONSIDERATION OF CERTAIN MAT-
11 TERS.—

12 “(i) IN GENERAL.—Not later than 18
13 months after the date of the enactment of
14 the Protection for Participants in Research
15 Act of 2006, the Secretary shall, with re-
16 spect to the Common Rule—

17 “(I) consider the matters speci-
18 fied in clause (ii) and make a deter-
19 mination of whether any of the provi-
20 sions of such Rule should be modified
21 accordingly; and

22 “(II) publish the determination
23 in the Federal Register.

24 “(ii) LIST OF MATTERS FOR CONSID-
25 ERATION.—The matters referred to in

1 clause (i) with respect to the Common
2 Rule are the following:

3 “(I) Whether the list of exemptions
4 from applicability of the Common Rule, as
5 in effect on the day before the date of en-
6 actment referred to in clause (i), should be
7 modified or new categories of exemptions
8 established.

9 “(II) Whether there are circumstances
10 in which research that studies human tis-
11 sue or other types of clinical specimens
12 should not be considered human subject re-
13 search.

14 “(III) Whether research that studies
15 data that do not involve any interaction or
16 intervention with a living human should be
17 considered human subject research.

18 “(IV) Whether the list of expedited
19 procedures under the Common Rule, as in
20 effect on the day before the date of enact-
21 ment referred to in clause (i), should be
22 modified or new categories of expedited
23 procedures established.

24 “(V) Whether modified procedures
25 should apply to human subject research

1 that poses minimal risk to the subjects, in-
2 cluding whether there are any types of
3 such research for which some aspect of the
4 requirement of informed consent or docu-
5 mentation of informed consent should
6 apply differently.

7 “(VI) Whether Institutional Review
8 Boards include sufficient numbers of mi-
9 nority individuals (as defined in section
10 485E(c)) as Board members when review-
11 ing proposals designed to have a popu-
12 lation of human subjects a majority of
13 whom are minority individuals.

14 “(VII) Such additional matters as the
15 Secretary determines to be appropriate.

16 “(D) AGENCY-SPECIFIC ADDITIONAL PRO-
17 TECTIONS.—With respect to human subject re-
18 search that is conducted, supported, or other-
19 wise subject to regulation under a provision of
20 Federal law (other than this section), the Sec-
21 retary may under subparagraph (A) permit the
22 Federal agency involved to establish additional
23 protections for the protection of human subjects
24 if the Secretary determines that such additional

1 protections are not in conflict with protections
2 established under this section.

3 “(d) RIGHT OF INFORMED CONSENT.—

4 “(1) IN GENERAL.—For purposes of subsection
5 (a), a principal investigator, may not, except as pro-
6 vided in the Common Rule, involve an individual as
7 a subject in human subject research unless the in-
8 vestigator or other knowledgeable person has ob-
9 tained the informed consent of the individual to be
10 a subject.

11 “(2) LEGALLY AUTHORIZED REPRESENTA-
12 TIVE.—References in this section to obtaining con-
13 sent from an individual shall be considered to be ref-
14 erences to obtaining consent from the legally author-
15 ized representative of the individual in any case in
16 which the individual lacks legal competence to pro-
17 vide consent.

18 “(3) CERTAIN REQUIREMENTS REGARDING DIS-
19 CLOSURE AND UNDERSTANDING.—The Secretary
20 shall establish criteria regarding consent under para-
21 graph (1) that—

22 “(A) provide for the provision of full and
23 complete information relevant to the research to
24 a prospective human subject;

1 “(B) require such information to be pro-
2 vided in language understandable to such sub-
3 ject;

4 “(C) require that only individuals knowl-
5 edgeable about the research provide such infor-
6 mation to the subject and answer questions
7 from the subject; and

8 “(D) require that information be provided
9 to the subject on how to contact the Office for
10 Human Research Protections to submit ques-
11 tions about the rights of subjects or to report
12 concerns regarding the research.

13 “(4) WRITTEN ATTESTATION BY INVESTI-
14 GATOR.—A principal investigator who involves a
15 human subject in research shall, in accordance with
16 the criteria of the Secretary, file with the Institu-
17 tional Review Board for the research a written attes-
18 tation that the investigator is familiar with require-
19 ments for the protection of human subjects, includ-
20 ing the requirement of informed consent, and agrees
21 to comply with such requirements.

22 “(e) INSTITUTIONAL REVIEW BOARDS.—

23 “(1) REQUIREMENTS FOR BOARDS.—Human
24 subject research may not be conducted unless an In-
25 stitutional Review Board has, for purposes of the

1 Common Rule (and the vulnerable-populations rules,
2 as applicable), approved the proposal for such re-
3 search. With respect to the research involved, the
4 approval by the Board of the proposal for the re-
5 search is not effective unless, in addition to condi-
6 tions established by the Secretary, the following con-
7 ditions are met:

8 “(A) Of the membership of such Board:

9 “(i) Not fewer than two members or
10 25 percent of all members, whichever is
11 greater, are individuals whose primary ex-
12 pertise is in scientific areas.

13 “(ii) Not fewer than two members or
14 20 percent of all members (whichever is
15 greater) are individuals whose primary ex-
16 pertise is in nonscientific areas.

17 “(iii) Not fewer than two members or
18 20 percent of all members (whichever is
19 greater) are individuals who are not affili-
20 ated with the institution served by the
21 Board (other than by serving on the
22 Board), who are not immediate family
23 members of any individual who is affiliated
24 with the institution, and who do not have

1 a significant conflict of interest, as defined
2 by applicable Federal regulations.

3 The appointment of a member of the Board to
4 meet the requirement of clause (iii) also quali-
5 fies toward meeting the requirement of clause
6 (ii) if the primary expertise of such member is
7 in a nonscientific area.

8 “(B) In reviewing a proposal for research,
9 the Board does not consider a quorum to have
10 been established for a meeting unless the mem-
11 bers present at the meeting include one or more
12 members from each of the three categories de-
13 scribed in subparagraph (A).

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

21 “(D) The institution served by the Board
22 has submitted to the Secretary a registration
23 informing the Secretary of the existence of the
24 Board, and the registration was in such form,
25 was made in such manner, and contained such

1 information as the Secretary requested regard-
2 ing functions of the Board under this section.

3 “(E) In the case of a proposal for a high-
4 risk research project, the Board reviews the
5 data safety and monitoring plan (pursuant to
6 subsection (f)) as a part of the review by the
7 Board of the proposal.

8 “(F) With respect to the research involved,
9 each member of the Board has disclosed any
10 significant financial interests, as defined by ap-
11 plicable Federal regulations, to the institution
12 served by the Board, and such institution has
13 disclosed any such disclosures to the Board.

14 “(G) A member of the Board does not par-
15 ticipate in the review by the Board of a pro-
16 posal for research if the member has a signifi-
17 cant conflict of interest, as defined by applica-
18 ble Federal regulations, in the research. The
19 provision by such member of information to
20 other members of the Board does not constitute
21 Board participation for purposes of this sub-
22 paragraph.

23 “(H) The institution served by the Board
24 annually submits to the Secretary a report that
25 compiles data on the number of new research

1 proposals reviewed, the number of continuing
2 research projects reviewed, the number of re-
3 viewed biomedical research proposals, the num-
4 ber of reviewed behavioral or social sciences re-
5 search proposals, and any additional informa-
6 tion determined appropriate by the Secretary.

7 “(I) The institution served by the Board
8 submits to the Secretary such reports regarding
9 the Board as the Secretary determines to be ap-
10 propriate.

11 “(2) NOTIFICATION OF INSTITUTIONAL REVIEW
12 BOARD BY INVESTIGATORS.—In submitting to an In-
13 stitutional Review Board a proposal for human sub-
14 ject research, the investigators for the research shall
15 notify the institution served by the Board—

16 “(A) of any significant financial conflicts
17 of interest, as defined by applicable Federal
18 regulations;

19 “(B) whether the investigators have been
20 disqualified or restricted by any Federal entity
21 in their ability to conduct human subject re-
22 search, including being ineligible to conduct
23 human subject research with investigational
24 new drugs, being ineligible for approval of new

1 drug applications, or agreeing to some other
2 form of restriction regarding research; and

3 “(C) whether the proposal has been sub-
4 mitted by the principal investigator to any other
5 Institutional Review Board.

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

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

21 “(5) VOLUNTARY ACCREDITATION.—The Sec-
22 retary may in accordance with this paragraph facili-
23 tate the accreditation of institutions and Institu-
24 tional Review Boards by recognizing a private ac-

1 crediting entity or entities. For purposes of the pre-
2 ceding sentence:

3 “(A) The Secretary may recognize an ac-
4 crediting entity if—

5 “(i) such entity submits to the Sec-
6 retary the standards and procedures that
7 the entity requires institutions and Institu-
8 tional Review Boards to meet in order to
9 be accredited by the entity;

10 “(ii) the Secretary determines that
11 such standards and procedures include
12 standards and procedures ensuring that
13 the policies and procedures of institutions
14 and Institutional Review Boards accredited
15 by the entity are in compliance with Fed-
16 eral regulations governing human subject
17 research; and

18 “(iii) the entity annually submits to
19 the Secretary a report describing any
20 changes in the standards and procedures
21 described in clause (ii).

22 “(B) The Secretary may not require that
23 any institution, Institutional Review Board, or
24 program for the protection of human subjects

1 in research, or any component thereof, be ac-
2 credited.

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

5 “(i) to establish or approve accredita-
6 tion standards or procedures for institu-
7 tions, Institutional Review Boards, or pro-
8 grams for the protection of human subjects
9 in research, or any component thereof; or

10 “(ii) to recognize any standards or
11 procedures for institutions or Institutional
12 Review Boards other than the standards
13 and procedures described in subparagraph
14 (A)(ii).

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

19 “(f) IMPROVED MONITORING OF HIGH-RISK RE-
20 SEARCH.—With respect to high-risk human subject re-
21 search projects:

22 “(1) The Secretary shall establish criteria for
23 identifying proposals for such projects that require
24 a data safety and monitoring plan. The criteria shall
25 include—

1 “(A) a provision that the Secretary may
2 require the sponsor of the project to utilize a
3 data safety and monitoring committee in affili-
4 ation with the research project;

5 “(B) minimum requirements for the re-
6 porting by the principal investigator of informa-
7 tion on such plan to the Institutional Review
8 Board for the research project and to the insti-
9 tution served by the Board; and

10 “(C) the requirement that such committee
11 provide reports on the findings of the com-
12 mittee regarding the research project to such
13 investigator, Board, and institution.

14 “(2) The Secretary shall require that an ad-
15 verse event in the research project be reported by
16 the principal investigator to the Institutional Review
17 Board for the research project, and to the sponsor
18 of the research project, in a timely manner appro-
19 priate to the severity of the event and whether the
20 event is unexpected. Such events shall in addition be
21 reported by the principal investigator as directed by
22 the Secretary. Such regulations shall ensure com-
23 prehensive and coordinated reporting to all relevant
24 parties.

1 “(g) INSTITUTIONAL PROGRAMS OF EDUCATION.—
2 For fiscal year 2007 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 2006.”.

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)(C) 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.—If the Director de-
4 termines that an Institutional Review Board is
5 not in compliance with the Common Rule, the
6 Director may—

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

15 “(ii) may provide that all approvals of
16 research by the Board are not effective for
17 purposes of such section, in any case in
18 which the Director determines that the
19 noncompliance creates a significant threat
20 to the rights and welfare of human sub-
21 jects in projects approved by the Board.

22 “(D) PROJECTS INVOLVING MULTIPLE LO-
23 CATIONS.—In the case of a project of human
24 subject research for which there is an agree-
25 ment described in section 491A(b)(4)(F) (relat-

1 ing to multiple Institutional Review Boards),
2 the Director of the Office shall, in carrying out
3 authorities under this subsection with respect to
4 an Institutional Review Board, ensure that no
5 action is taken that adversely affects the oper-
6 ation of a project of human subject research at
7 any project location for which such Institutional
8 Review Board had no responsibilities.

9 “(5) NOTIFICATION OF FEDERAL AND STATE
10 REGULATORY AGENCIES.—In any case in which the
11 Director of the Office takes an action described in
12 paragraph (3)(E) or (4)(C)(ii) against an entity that
13 conducts or supports human subject research, or
14 against an Institutional Review Board, respectively,
15 the Director shall notify relevant Federal and State
16 regulatory agencies, and as applicable, the sponsors
17 of the research, of the deficiencies in the operation
18 of the entity or Board.

19 “(6) COORDINATION WITH FOOD AND DRUG AD-
20 MINISTRATION.—In the case of human subject re-
21 search that is subject to the Federal Food, Drug,
22 and Cosmetic Act or to section 351 of this Act, no
23 authority under this subsection may be carried out
24 with respect to an entity that conducts or supports
25 such research, or with respect to an Institutional Re-

1 view Board, unless the Commissioner of Food and
2 Drugs concurs in the exercise of the authority in-
3 volved.

4 “(e) FUNDING.—

5 “(1) AUTHORIZATION OF APPROPRIATIONS.—

6 For the purpose of carrying out this section, there
7 are authorized to be appropriated \$20,000,000 for
8 fiscal year 2007, and such sums as may be nec-
9 essary for fiscal year 2008 and each subsequent fis-
10 cal year.

11 “(2) MODEL EDUCATION PROGRAM.—For the

12 purpose of carrying out subsection (c), there are au-
13 thorized to be appropriated such sums as may be
14 necessary for fiscal year 2007 and each subsequent
15 fiscal year.

16 “(3) RULE OF CONSTRUCTION.—Nothing in

17 this section or section 491A may be construed as a
18 change in the budget authority or authorization of
19 appropriations for the Food and Drug Administra-
20 tion.”.

21 **SEC. 4. AMENDMENTS REGARDING PROCESS FOR RE-**

22 **SPONDING TO REPORTS OF VIOLATIONS.**

23 Section 491(b)(2) of the Public Health Service Act
24 (42 U.S.C. 289(b)(2)) is amended—

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

4 (2) in the second sentence, by inserting after
5 “this Act” the following: “, the sharing of informa-
6 tion between the Director of NIH and the Director
7 of such Office, and”.

8 **SEC. 5. ENHANCED HUMAN SUBJECT PROTECTIONS FOR**
9 **PEOPLE WITH DIMINISHED DECISIONMAKING**
10 **CAPACITY.**

11 Not later than three years after the date of the enact-
12 ment of this Act, the Secretary of Health and Human
13 Services shall, for purposes of section 491A of the Public
14 Health Service Act, promulgate regulations to enhance the
15 protection of people with diminished decisionmaking ca-
16 pacity with respect to their participation as subjects in
17 human subject research.

18 **SEC. 6. RULE OF CONSTRUCTION REGARDING INDIVIDUAL**
19 **AGENCY OFFICES.**

20 The amendments made by this Act may not be con-
21 strued as terminating any office or other administrative
22 unit in a Federal agency that, on the day before the date
23 of the enactment of this Act, had duties relating to the
24 protection of human subjects in research conducted, sup-

1 ported, or otherwise subject to regulation under Federal
2 law.

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