

107<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 4697

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

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IN THE HOUSE OF REPRESENTATIVES

MAY 9, 2002

Ms. DEGETTE (for herself and Mr. GREENWOOD) introduced the following bill;  
which was referred to the Committee on Energy and Commerce

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## 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 “Human Research Sub-  
5 ject Protections Act of 2002”.

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 “PROTECTION OF HUMAN SUBJECTS; UNIFORM NATIONAL  
9 APPLICABILITY OF COMMON RULE AND PROVISIONS  
10 PROTECTING VULNERABLE POPULATIONS

11 “SEC. 491A. (a) PROTECTION OF HUMAN SUB-  
12 JECTS.—

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                   subpart D of part 50 of such title 21 (or  
6                   any successor regulations).

7                   “(C) In the case of human subject research  
8                   to which both of subparagraphs (A) and (B)  
9                   apply, the terms ‘common rule’ and ‘vulnerable-  
10                  population rules’ have the meaning given such  
11                  terms in subparagraph (B).

12                  “(2) HARMONIZATION.—

13                  “(A) REVIEW OF REGULATIONS.—Not  
14                  later than 18 months after the date of the en-  
15                  actment of the Human Research Subject Pro-  
16                  tections Act of 2002, the Secretary shall com-  
17                  plete a review of the provisions of subpart A of  
18                  part 46 of title 45, Code of Federal Regulations  
19                  (referred to in this paragraph as ‘title 45 regu-  
20                  lations’), and the provisions of parts 50 and 56  
21                  of title 21, Code of Federal Regulations (re-  
22                  ferred to in this paragraph as ‘title 21 regula-  
23                  tions’), in order to determine to what extent the  
24                  differences in approach between the title 45  
25                  regulations and the title 21 regulations can be

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

13 “(B) RULEMAKING.—

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

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

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

23                   “(A) Except as provided in subparagraphs  
24                   (B) and (C):

1           “(i) The term ‘human subject re-  
2           search’ means clinical research that is con-  
3           ducted with the direct involvement of one  
4           or more human subjects.

5           “(ii) For purposes of the definition es-  
6           tablished in clause (i), the term ‘research’  
7           has the meaning that applies for purposes  
8           of part 46 of title 45, Code of Federal  
9           Regulations (or any 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 research’  
14          means clinical research that is a clinical inves-  
15          tigation within the meaning of such part 50, ex-  
16          cept as provided in subparagraph (C).

17          “(C) The term ‘human subject research’  
18          does not include the collection, analysis, or ab-  
19          straction of data contained in records that were  
20          made for purposes other than research or inves-  
21          tigations conducted with human subjects, in-  
22          cluding but not limited to business, health, fi-  
23          nancial, research, marketing, survey, education,  
24          or government records.

1           “(D) The term ‘clinical research’ has the  
2 meaning given such term in section 409(b).

3           “(E) The term ‘human subject’ means a  
4 living human being.

5           “(4) OTHER DEFINITIONS.—For purposes of  
6 this section:

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

11           “(i) specifically authorized under cri-  
12 teria established by an Executive order to  
13 be kept secret in the interest of national  
14 defense or foreign policy; and

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

17           “(B) The term ‘data monitoring com-  
18 mittee’, with respect to human subject research  
19 that is a clinical trial, means a group of individ-  
20 uals with appropriate expertise that, on an on-  
21 going basis during the conduct of such trial—

22           “(i) reviews data that is generated  
23 during the trial;

1           “(ii) advises the sponsor regarding the  
2           continuing safety of human subjects who  
3           are or will be participating in the trial; and

4           “(iii) advises such sponsor on the con-  
5           tinued validity and scientific merit of the  
6           trial.

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

10           “(D) The term ‘institution served by an  
11           Institutional Review Board’ means the public or  
12           private entity (university, health care provider,  
13           health plan, research organization, government  
14           agency, or other entity) that establishes and is  
15           responsible for the operation of the Institutional  
16           Review Board.

17           “(E) The term ‘Institutional Review  
18           Board’ has the meaning that applies under the  
19           common rule.

20           “(F) The term ‘lead Institutional Review  
21           Board’ means an Institutional Review Board  
22           that otherwise meets the requirements of the  
23           common rule and enters into a written agree-  
24           ment with an institution, another Institutional  
25           Review Board, a sponsor, or a principal investi-

1 gator to approve and oversee human subject re-  
2 search that is conducted at multiple locations.  
3 For purposes of this section, references to an  
4 Institutional Review Board include an Institu-  
5 tional Review Board that serves a single institu-  
6 tion as well as a lead Institutional Review  
7 Board.

8 “(G) The term ‘principal investigator’,  
9 with respect to human subject research, means  
10 the individual who, at the research location in-  
11 volved, has the principal responsibility for the  
12 conduct of the research.

13 “(H)(i) Except as provided in clause (ii),  
14 the term ‘sponsor’, with respect to human sub-  
15 ject research, means the entity that has the  
16 principal financial responsibility for the conduct  
17 of the research.

18 “(ii) In the case of an investigation that is  
19 subject to the provisions of part 50 of title 21,  
20 Code of Federal Regulations (or successor regu-  
21 lations), the term ‘sponsor’, with respect to  
22 human subject research, has the meaning that  
23 applies for purposes of such part 50.

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

1           “(1) IN GENERAL.—The common rule (includ-  
2           ing provisions regarding exemptions) and the vulner-  
3           able-populations rules, as in effect on the day before  
4           the date of the enactment of the Human Research  
5           Subject Protections Act of 2002, continue to be in  
6           effect on and after such date, subject to paragraph  
7           (2).

8           “(2) MODIFICATIONS.—

9           “(A) COMPLIANCE WITH LAW.—Promptly  
10           after the date of the enactment of the Act re-  
11           ferred to in paragraph (1), the Secretary shall  
12           promulgate regulations to make such modifica-  
13           tions to the provisions of the common rule as  
14           may be necessary to ensure that such provisions  
15           implement, and do not conflict with, this sec-  
16           tion.

17           “(B) OTHER MODIFICATIONS.—This sec-  
18           tion may not be construed as affecting the au-  
19           thority of the Secretary to modify the provisions  
20           of the common rule or the vulnerable-popu-  
21           lations rules, except to the extent that any such  
22           modification is in conflict with this section. Any  
23           such modification shall be made by regulation.

24           “(C) AGENCY-SPECIFIC ADDITIONAL PRO-  
25           TECTIONS.—With respect to human subject re-

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

10 “(d) RIGHT OF INFORMED CONSENT.—

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

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

1           “(3) CONSENT FORM.—The consent of an indi-  
2           vidual to be a human subject in human subject re-  
3           search shall be documented by the principal investi-  
4           gator for the research or another knowledgeable per-  
5           son, and such documentation shall include an ac-  
6           knowledge by such individual that the indi-  
7           vidual has with respect to the research been provided  
8           a written explanation of the following:

9                   “(A) The purpose of the research.

10                   “(B) The potential risks and benefits of  
11           being a subject in the research.

12                   “(C) As applicable to the research, the dif-  
13           ference between research and therapeutic treat-  
14           ment.

15                   “(D) The right to cease participation as a  
16           subject at any time.

17                   “(E) The identity of the sponsors of the  
18           research.

19                   “(F) Any conflict of interest that the in-  
20           vestigators have in the research.

21                   “(G) As applicable to the research, the  
22           medical tests and procedures that may be nec-  
23           essary as part of the research, and the extent  
24           to which the costs of such tests and procedures

1 will not be paid by the sponsor or other entities  
2 involved in the research.

3 “(H) Such additional information as the  
4 Secretary may require.

5 “(4) CERTAIN REQUIREMENTS REGARDING DIS-  
6 CLOSURE AND UNDERSTANDING.—The Secretary  
7 shall establish criteria regarding consent under para-  
8 graph (1) that provide for the following:

9 “(A) During the process of obtaining con-  
10 sent, a prospective human subject is, through  
11 the written explanation provided under para-  
12 graph (2) and through written or oral answers  
13 to questions from the prospective subject, pro-  
14 vided full and complete information relevant to  
15 the research involved.

16 “(B) Such information is provided to the  
17 prospective subject in the language and in a  
18 manner that allows the subject to understand  
19 the information and make an informed decision,  
20 free of coercion, regarding participation as a  
21 human subject.

22 “(C) Only an individual who is knowledge-  
23 able about the research, and can reasonably be  
24 expected to be able to answer questions from

1 the subject regarding the research, is author-  
2 ized to provide such information to the subject.

3 “(D) The written statement under para-  
4 graph (2) provides the information required in  
5 such paragraph in a clear and conspicuous  
6 manner.

7 “(E) A copy of the documentation of the  
8 consent of the subject is provided to the sub-  
9 ject, together with information on how to con-  
10 tact the Office of Human Research Protections  
11 to submit questions about subjects’ rights or to  
12 report concerns regarding the research.

13 “(5) 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 conflict of interest (including nonpropri-  
2           etary interest).

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) When reviewing a proposal for re-  
9           search that is designed to include as a subject  
10          an individual who is a member of a vulnerable  
11          population, the Board includes at least one  
12          member who is an expert in the issues involving  
13          such population; allows such member to fully  
14          participate in the Board review process; and  
15          provides such member with the same voting  
16          rights as other members of the Board. The ap-  
17          pointment of a member of the Board to meet  
18          the requirement of this subparagraph may also  
19          qualify toward meeting the requirement of  
20          clause (ii) of subparagraph (A), or clause (iii)  
21          of such subparagraph, if such member satisfies  
22          the criteria described in the clause involved.

23          “(C) When reviewing a proposal for re-  
24          search that is designed to include as subjects a  
25          significant number of minority individuals (as

1 defined in section 485E(c)), the Board includes  
2 minority members; allows such members to fully  
3 participate in the Board review process; and  
4 provides such members with the same voting  
5 rights as other members of the Board. The ap-  
6 pointment of a member of the Board to meet  
7 the requirement of this subparagraph may also  
8 qualify toward meeting the requirement of  
9 clause (ii) of subparagraph (A), or clause (iii)  
10 of such subparagraph, if such member satisfies  
11 the criteria described in the clause involved.

12 “(D)(i) In reviewing a proposal for re-  
13 search, the Board does not consider a quorum  
14 to have been established for a meeting unless  
15 the members present at the meeting include one  
16 or more members from each of the three cat-  
17 egories described in subparagraph (A).

18 “(ii) In any case in which the Board will  
19 under subparagraph (C) review a proposal for  
20 research that is designed to include as subjects  
21 a significant number of minority individuals,  
22 the Board does not consider a quorum to have  
23 been established for a meeting unless the mem-  
24 bers present at the meeting include the mem-  
25 bers required under such subparagraph.

1           “(E) The institution served by the Board  
2 ensures that the Board has an orientation pro-  
3 gram for new members and a continuing edu-  
4 cation program for existing members of the  
5 Board, and with respect to ethical matters that  
6 relate to research, a continuing education pro-  
7 gram for all members of the Board.

8           “(F) The institution served by the Board  
9 has submitted to the Secretary a registration  
10 informing the Secretary of the existence of the  
11 Board, and the registration was in such form,  
12 was made in such manner, and contained such  
13 information as the Secretary requested regard-  
14 ing functions of the Board under this section.

15           “(G) In the case of a proposal for a high  
16 risk trial, the Board reviews the data safety and  
17 monitoring plan of the data monitoring com-  
18 mittee (operated pursuant to subsection (f)) as  
19 a part of the review by the Board of the pro-  
20 posal.

21           “(H) With respect to the research involved,  
22 each member of the Board has disclosed to the  
23 institution served by the Board, and such insti-  
24 tution has disclosed to the Board, any actual  
25 conflicts of interest, or interests that create the

1 appearance of a conflict of interest, with respect  
2 to such research, including (but not limited  
3 to)—

4 “(i) involvement as investigators in  
5 the research;

6 “(ii) ownership interests in the re-  
7 search; and

8 “(iii) direct financial relationships or  
9 arrangements with private sponsors of the  
10 research, excluding ownership of any inde-  
11 pendently-managed investment plan (such  
12 as mutual funds) that may own a financial  
13 interest in such a sponsor.

14 “(I) 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 conflict  
17 of interest (including a nonproprietary interest)  
18 in the research. The provision by such member  
19 of information to other members of the Board  
20 does not constitute Board participation for pur-  
21 poses of this subparagraph.

22 “(J) The institution served by the Board  
23 annually submits to the Secretary a report that  
24 compiles data on the number of new research  
25 proposals reviewed, the number of continuing

1 research projects reviewed, the number of  
2 human subjects involved in approved research,  
3 and any additional information determined ap-  
4 propriate by the Secretary.

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

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

15 “(A) of any actual conflicts of interest, or  
16 interests that create the appearance of a con-  
17 flict of interest;

18 “(B) whether the investigators have been  
19 disqualified or restricted by any Federal entity  
20 in their ability to conduct human subject re-  
21 search, including being ineligible to conduct  
22 human subject research with investigational  
23 new drugs, being ineligible for approval of new  
24 drug applications, or agreeing to some other  
25 form of restriction regarding research; and

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

4           “(3) INSTITUTION REVIEW OF CONFLICTS OF  
5           INTEREST.—The institution served by an Institu-  
6           tional Review Board shall review such conflicts of in-  
7           terest or interests that create the appearance of a  
8           conflict of interest as are submitted under para-  
9           graph (2) and shall seek to reduce or eliminate and  
10          shall oversee such conflicts of interest, with respect  
11          to the research.

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

19          “(5) VOLUNTARY ACCREDITATION.—The Sec-  
20          retary may in accordance with this paragraph facili-  
21          tate the accreditation of Institutional Review Boards  
22          and institutions by a private accrediting entity or  
23          entities. For purposes of the preceding sentence:

24                  “(A) The Secretary may recognize an ac-  
25                  crediting entity if the accrediting entity submits

1 to the Secretary the accrediting standards of  
2 the entity, the Secretary determines that the  
3 standards further the purposes of this section,  
4 and the accrediting entity annually submits to  
5 the Secretary a report describing any changes  
6 in the accrediting standards or procedures of  
7 the entity.

8 “(B) The Secretary shall biannually evalu-  
9 ate the performance of the accrediting entity.

10 “(C) The Secretary may withdraw recogni-  
11 tion of the accrediting entity if the Secretary  
12 determines that the requirements of subpara-  
13 graph (A) are not met.

14 “(D) The Secretary may not require that  
15 any Institutional Review Board be accredited.

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

20 “(f) IMPROVED MONITORING OF HIGH RISK CLIN-  
21 ICAL TRIALS.—With respect to human subjects in high  
22 risk clinical trials:

23 “(1) The Secretary shall establish criteria for  
24 identifying high risk clinical trials requiring a data

1 safety and monitoring plan for each such trial. The  
2 criteria shall include—

3 “(A) a provision that the Secretary may  
4 require the sponsor of the trial to utilize a data  
5 monitoring committee in affiliation with the  
6 trial;

7 “(B) minimum requirements for the re-  
8 porting by the principal investigator of informa-  
9 tion on such plan to the Institutional Review  
10 Board for the trial and to the institution served  
11 by the Board; and

12 “(C) the requirement that such committee  
13 provide reports on the findings of the com-  
14 mittee regarding the trial to such investigator,  
15 Board, and institution.

16 “(2) The Secretary shall require that adverse  
17 events in such a trial be reported by the principal  
18 investigator for the trial in a timely manner appro-  
19 priate to whether the event is unexpected and its se-  
20 verity to the Institutional Review Board for the trial,  
21 and to the sponsor of the trial. Such events shall in  
22 addition be reported by the principal investigator to  
23 the Director of the Office of Human Research Pro-  
24 tections, or the Commissioner of Food and Drugs,  
25 whichever administers the common rule as applied to

1 the trial. Such regulations shall ensure comprehen-  
2 sive and coordinated reporting to all relevant parties.

3 “(g) INSTITUTIONAL PROGRAMS OF EDUCATION.—

4 For fiscal year 2003 and subsequent fiscal years, the Sec-  
5 retary may not make an award of a grant, cooperative  
6 agreement, or contract under this Act to a public entity  
7 or a private academic institution, or make an award of  
8 a grant, cooperative agreement, or contract under this Act  
9 for the conduct of research at or through or in affiliation  
10 with a public entity or a private academic institution, un-  
11 less the public entity or private academic institution (as  
12 the case may be) maintains or contracts for a comprehen-  
13 sive and ongoing program to educate investigators and  
14 Board members on the protection of human subjects in  
15 research.

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

20 “(1) the Institutional Review Board reviewing  
21 the proposal for the research pursuant to this sec-  
22 tion has under the common rule waived the require-  
23 ment to obtain the informed consent of the human  
24 subjects in the research; or

1           “(2) the research is exempt from the require-  
2           ment under the common rule that the proposal for  
3           the research be reviewed by such a Board.

4           “(i) DISCLOSURE OF VIOLATIONS.—

5           “(1) DISCLOSURES.— Upon the request of an  
6           entity that conducts or supports research, or upon  
7           the request of an Institutional Review Board, the  
8           Secretary shall determine whether another entity  
9           (including an individual, as applicable under the re-  
10          quest) has violated any requirement under this sec-  
11          tion, and shall disclose to such entity or Board the  
12          findings of the Secretary.

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

20          “(j) APPLICABILITY OF REQUIREMENTS.—The re-  
21          quirements of this section apply on and after the date of  
22          the enactment of the Human Research Subject Protec-  
23          tions Act of 2002.”.

1 **SEC. 3. OFFICE OF HUMAN RESEARCH PROTECTIONS.**

2 Part H of title IV of the Public Health Service Act  
3 (42 U.S.C. 289 et seq.), as amended by section 2 of this  
4 Act, is amended by inserting after section 491A the fol-  
5 lowing section:

6 “OFFICE OF HUMAN RESEARCH PROTECTIONS

7 “SEC. 491B. (a) IN GENERAL.—There is established  
8 within the Office of the Secretary an office to be known  
9 as the Office of Human Research Protections (in this sec-  
10 tion referred to as the ‘Office’). The Office shall be headed  
11 by a director, who shall be appointed by the Secretary.  
12 The Secretary shall carry out this section acting through  
13 the Director of the Office.

14 “(b) CERTAIN DUTIES.— The Director of the  
15 Office—

16 “(1) shall provide for the protection of human  
17 subjects in research by carrying out activities in ac-  
18 cordance with subsection (c) regarding compliance  
19 with the common rule, as defined in and modified  
20 pursuant to section 491A;

21 “(2) shall establish criteria regarding assur-  
22 ances of compliance with the requirements of the  
23 common rule;

24 “(3) shall coordinate activities within the De-  
25 partment of Health and Human Services, and co-  
26 ordinate the activities of the Department with other

1 Federal departments and agencies, with respect to  
2 the protection of human subjects in human subject  
3 research;

4 “(4) may, in collaboration with the Director of  
5 NIH and the Commissioner of Food and Drugs,  
6 carry out educational and quality improvement pro-  
7 grams for human subject protections for principal  
8 investigators, members of Institutional Review  
9 Boards, and other appropriate persons, including the  
10 generation of resource materials relating to the re-  
11 sponsibilities of the research community for the pro-  
12 tection of human subjects in research;

13 “(5) shall, upon the request of an entity that  
14 conducts or supports human subject research, con-  
15 sult with the entity regarding improvements in  
16 human subject protections in such research;

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)(E) and to develop best practices  
10          in institutional management of clinical trials.

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 ex-  
5           tent 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 de-  
16 scribed 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 under section 491A(b)(4)(F) (relating to

1 multiple Institutional Review Boards), the Di-  
2 rector of the Office shall, in carrying out au-  
3 thorities 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 2003, and such sums as may be nec-  
9 essary for fiscal year 2004 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 2003 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 of 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. NATIONAL RESEARCH PROTECTIONS ADVISORY**  
9 **COMMITTEE.**

10 The Secretary of Health and Human Services shall  
11 ensure the continuing operation of the National Research  
12 Protections Advisory Committee in accordance with the  
13 provisions for the operation of such Committee that were  
14 established by the Secretary on June 6, 2000, and were  
15 amended by the Secretary on January 19, 2001.

16 **SEC. 6. ENHANCED HUMAN SUBJECT PROTECTIONS FOR**  
17 **PEOPLE WITH DIMINISHED DECISIONMAKING**  
18 **CAPACITY.**

19 Not later than three years after the date of the enact-  
20 ment of this Act, the Secretary of Health and Human  
21 Services shall, for purposes of section 491A of the Public  
22 Health Service Act, promulgate regulations to enhance the  
23 protection of people with diminished decisionmaking ca-  
24 pacity with respect to their participation as subjects in  
25 human subject research.

1 **SEC. 7. RULE OF CONSTRUCTION REGARDING INDIVIDUAL**  
2 **AGENCY OFFICES.**

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

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