

107TH CONGRESS
2^D SESSION

S. 3060

To amend the Public Health Service Act to provide protections for human participants in research.

IN THE SENATE OF THE UNITED STATES

OCTOBER 4, 2002

Mr. KENNEDY introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to provide protections for human participants 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 “Research Revitaliza-
5 tion Act of 2002”.

6 **SEC. 2. FINDINGS AND PURPOSES.**

7 (a) FINDINGS.—The Congress finds as follows:

8 (1) In 1948, through adoption of the Universal
9 Declaration of Human Rights, the nations of the
10 world affirmed the Nuremberg Code which required

1 the ethical treatment of persons who serve as human
2 subjects in research.

3 (2) In response to findings of intolerable ethical
4 abuses of human subjects in research sponsored by
5 the Public Health Service and other Federal agen-
6 cies, Congress enacted the National Research Act
7 (Public Law 93–348) to provide ethical protections
8 for human subjects in Federally sponsored research
9 and to create the National Commission for the Pro-
10 tection of Human Subjects of Biomedical and Be-
11 havioral Research.

12 (3) The National Commission for the Protec-
13 tion of Human Subjects of Biomedical and Behav-
14 ioral Research issued the Belmont Report, which
15 stated that the treatment of human subjects in re-
16 search should be based on the principles of respect
17 for persons, beneficence, and justice.

18 (4) In 1981, the Department of Health and
19 Human Services published regulations (part 46 of
20 title 45, Code of Federal Regulations) to protect
21 human participants in research that were based on
22 the principles developed by the Commission.

23 (5) Some agencies of the Federal government
24 sponsor research involving human participants, but
25 these agencies have not adopted human participant

1 protections or vulnerable-populations protections as
2 provided for in part 46 of title 45, Code of Federal
3 Regulations, specifically subparts B, C, and D.

4 (6) Research institutions that receive Federal
5 funds for conducting research involving human par-
6 ticipants are not required to apply the protections of
7 part 46 of title 45, Code of Federal Regulations, to
8 all research conducted at the institution. Many, but
9 not all, research institutions have voluntarily made
10 this commitment.

11 (7) No provision of United States law explicitly
12 requires that informed consent and independent re-
13 view of all research involving human participants be
14 obtained.

15 (8) Numerous experts report and reviews have
16 found that the current system of protections for
17 human participants needs to be revitalized and en-
18 hanced to keep pace with the changing nature of re-
19 search.

20 (9) In 1995, the President's Advisory Com-
21 mittee on Human Radiation Experiments found that
22 there are significant deficiencies in some aspects of
23 the current system for the protection of human par-
24 ticipants. In particular, the Committee found that

1 some consent forms currently in use are flawed in
2 morally significant aspects.

3 (10) In 1998 and 2000, the Department of
4 Health and Human Services's Inspector General
5 found that the effectiveness of the Institutional Re-
6 view Board system was "in jeopardy" and attention
7 needed to be directed to enhancing human partici-
8 pant protections for a widening scope of clinical in-
9 vestigation.

10 (11) The Inspector General found that Institu-
11 tional Review Boards "review too much, too quickly,
12 with too little expertise".

13 (12) In its report on research conducted within
14 the United States, the National Bioethics Advisory
15 Commission recommended significant revisions to
16 the current oversight structure for the protection of
17 research participants. Among other recommenda-
18 tions, the Commission recommended establishing a
19 central office for Federal policy on research partici-
20 pant protections, enacting legislation to ensure that
21 all human participants are covered by ethical protec-
22 tions regardless of the funding source that supports
23 the research, as well as new policies to revitalize In-
24 stitutional Review Boards.

1 (13) In its report on international research, the
2 National Bioethics Advisory Commission found that
3 investigators have special responsibilities when con-
4 ducting research on participants from economically
5 less developed communities. These responsibilities
6 include the need to ensure adequately the provision
7 of informed consent in diverse communities and the
8 consideration of whether participants will benefit
9 from the results of such research when it is con-
10 cluded.

11 (14) In light of this and other evidence, legisla-
12 tion is required to enhance the current system for
13 protecting research participants so that—

14 (A) the safety and wellbeing of human par-
15 ticipants is properly safeguarded; and

16 (B) research involving human participants
17 can continue to enhance knowledge and
18 progress.

19 (15)(A) Entities conducting and sponsoring re-
20 search involving human participants engage in and
21 affect interstate commerce.

22 (B) Information obtained through research in-
23 volving human participants affects products and
24 services that move in interstate commerce.

1 (C) Human participants travel regularly across
2 State lines in order to become involved in research
3 involving human participants.

4 (D) Institutions at which research involving
5 human participants is conducted employ scientists,
6 doctors, researchers, and other staff in an interstate
7 market, and contract for research and supplies in an
8 interstate market.

9 (E) Sponsors of research involving human par-
10 ticipants buy and sell products and services in an
11 interstate market.

12 (b) PURPOSE.—The purposes of this Act are—

13 (1) to provide a comprehensive set of protec-
14 tions for human participants in research;

15 (2) to promote more effective oversight of re-
16 search involving human participants;

17 (3) to prevent improper financial conflicts of in-
18 terest by those conducting or providing for the eth-
19 ical oversight of research; and

20 (4) to provide effective oversight of research in-
21 volving human participants that is conducted outside
22 the borders of the United States, but is otherwise
23 subject to the regulatory authority of the United
24 States.

1 **TITLE I—HUMAN PARTICIPANT**
 2 **PROTECTIONS**

3 **SEC. 101. CONSISTENT NATIONAL APPLICABILITY OF**
 4 **STANDARDS TO PROTECT HUMAN PARTICI-**
 5 **PANT IN RESEARCH, ESTABLISHMENT OF A**
 6 **NATIONAL OFFICE OF HUMAN RESEARCH**
 7 **PROTECTIONS.**

8 Section 491 of the Public Health Service Act (42
 9 U.S.C. 289) is amended to read as follows:

10 **“SEC. 491. CONSISTENT NATIONAL APPLICABILITY OF**
 11 **STANDARDS TO PROTECT HUMAN PARTICI-**
 12 **PANT IN RESEARCH, ESTABLISHMENT OF A**
 13 **NATIONAL OFFICE OF HUMAN RESEARCH**
 14 **PROTECTIONS.**

15 “(a) **ETHICAL PRINCIPLES FOR THE CONDUCT OF**
 16 **RESEARCH INVOLVING HUMAN PARTICIPANTS.**—It is the
 17 policy of Congress that all research involving human sub-
 18 jects (that is conducted in the United States, funded by
 19 the United States Government, or that is subject to Fed-
 20 eral regulatory review) should be conducted so as to en-
 21 sure that—

22 “(1) the foreseeable risks have been weighed
 23 against the anticipated benefits and the risks are de-
 24 termined to be reasonable and justified by the poten-
 25 tial benefits that may result;

1 “(2) the rights and welfare of the participant,
2 including privacy and the protection of the data con-
3 cerning such participant, are safeguarded;

4 “(3) in the case of research that involves more
5 than minimal risk to a human participant or partici-
6 pants enrolled in such research, there is a reasonable
7 likelihood that the populations in which the covered
8 research is conducted will benefit from the results of
9 the research;

10 “(4) the participant may, without any resulting
11 reprisal, withdraw from the covered research at any
12 time by revoking his or her informed consent;

13 “(5) informed consent in the appropriate man-
14 ner has been obtained;

15 “(6) situations that may render a participant
16 vulnerable to harm or coercion are identified and
17 minimized; and

18 “(7) those with responsibility for ensuring the
19 welfare of research participants are not subject to
20 conflicts of interest that may impair their ability to
21 discharge that responsibility effectively.

22 “(b) CONSISTENT NATIONAL APPLICABILITY OF
23 STANDARDS TO PROTECT HUMAN PARTICIPANTS IN RE-
24 SEARCH.—Effective beginning on June 1, 2005, no cov-

1 ered research may be conducted unless it is in accordance
2 with—

3 “(1) the provisions of part 46 (including all
4 subparts) of title 45, Code of Federal Regulations
5 (referred to in this part as ‘the common rule’), as
6 in effect on June 1, 2003; and

7 “(2) any amendments to such provisions under
8 subsection (d).

9 “(c) OFFICE OF HUMAN RESEARCH PROTECTIONS.—

10 “(1) ESTABLISHMENT.—There is established
11 within the Department of Health and Human Serv-
12 ices an office to be known as the Office of Human
13 Research Protections (in this section referred to as
14 the ‘Office’).

15 “(2) DIRECTOR.—The Office shall be headed by
16 a Director who shall be appointed by the Secretary,
17 with the advice and consent of the Senate including
18 submission of the nomination to the Committee on
19 Health, Education, Labor, and Pensions of the Sen-
20 ate for appropriate hearings. The term of office of
21 the Director shall be 6 years, except that the Sec-
22 retary may remove a Director who fails to carry out
23 the duties of the Director in good conduct. An indi-
24 vidual may be appointed to the office of Director for
25 no more than 2 terms.

1 “(d) AMENDMENTS TO THE COMMON RULE.—

2 “(1) IN GENERAL.—The Director may by regu-
3 lation amend the provisions of the common rule, ex-
4 cept to the extent that any such amendment is in
5 conflict with this section or any of sections 491A,
6 491B, 492B, and 492C.

7 “(2) CONSULTATIONS.—In promulgating regu-
8 lations under paragraph (1), the Director shall, to
9 the maximum extent practicable, consult with—

10 “(A) the Advisory Committee under sub-
11 section (e); and

12 “(B) the Human Subjects Research Sub-
13 committee of the National Science and Tech-
14 nology Council (or any successor to such Sub-
15 committee) to the extent that such sub-
16 committee is conducting business or meetings.

17 “(3) AUTHORITY FOR DETERMINATIONS.—The
18 Director may promulgate regulations under this sub-
19 section regarding—

20 “(A) whether research is covered research
21 under the meaning given that term under sec-
22 tion 492B(h)(2); and

23 “(B) whether covered research involves
24 greater than minimal risk under the meaning
25 given that term under section 492B(h)(8) and

1 is therefore eligible for administrative review as
2 specified in section 491A(c)(1).

3 “(4) CONGRESSIONAL FINDINGS.—

4 “(A) FINDING REGARDING RESEARCH
5 THAT INVOLVES LESS THAN MINIMAL RISK.—

6 Congress finds that much—

7 “(i) social science research; and

8 “(ii) other research that does not
9 involve—

10 “(I) the introduction of foreign
11 substances into the body of a human
12 participant or participants;

13 “(II) significant alterations of
14 the physical or sensory environment of
15 a human participant or participants;
16 or

17 “(III) significant risks to the pri-
18 vacy, dignity, or economic wellbeing of
19 a human participant or participants;

20 is likely to involve less than minimal risk under
21 the meaning of that term under section
22 492B(h)(8).

23 “(B) FINDING REGARDING RESEARCH IN-
24 VOLVING INDIVIDUALS WHO HAVE UNDERGONE
25 TRAUMA.—Congress finds that—

1 “(i) in circumstances in which an in-
2 dividual has undergone trauma, research
3 involving the individual often cannot prac-
4 tically be carried out with the consent of
5 the individual; and

6 “(ii) in such limited circumstances,
7 there are acceptable alternative means of
8 obtaining consent, as described in section
9 50.24 of title 21, Code of Federal Regula-
10 tions (as in effect on the day before the
11 date of enactment of the Research Revital-
12 ization Act of 2001).

13 “(5) RECOGNITION OF FINDING.—The Director
14 shall consider—

15 “(A) the finding under paragraph (4)(A)
16 in promulgating regulations under paragraph
17 (3)(B); and

18 “(B) the finding under paragraph (4)(B)
19 in promulgating regulations regarding informed
20 consent under paragraph (1).

21 “(e) ADVISORY COMMITTEE.—The Secretary shall es-
22 tablish a National Human Research Protections Advisory
23 Committee to serve as an Advisory Committee for pur-
24 poses of providing expert advice and counsel to the Sec-

1 retary on issues relating to or associated with the protec-
2 tion of human research participants.

3 “(f) CERTAIN ADMINISTRATIVE AUTHORITIES.—In
4 carrying out this section and sections 491A and 491B, the
5 Director of the Office may—

6 “(1) appoint and fix the compensation of offi-
7 cers and employees for the Office in accordance with
8 chapter 51 of title 5, United States Code, and sub-
9 chapter III of chapter 53 of such title;

10 “(2) acquire, without regard to the Act of
11 March 3, 1877 (40 U.S.C. 34), by lease or otherwise
12 through the Administrator of General Services,
13 buildings or portions of buildings in the District of
14 Columbia or communities located adjacent to the
15 District of Columbia for use for a period not to ex-
16 ceed 10 years;

17 “(3) enter into contracts, subject to the avail-
18 ability of amounts made available in appropriations
19 Acts, including contracts for financial and adminis-
20 trative services (such as budget and accounting, fi-
21 nancial reporting, personnel, and procurement), with
22 the General Services Administration, or such other
23 Federal agencies as the Director of the Office deter-
24 mines to be appropriate;

1 “(4) use, with their consent, the services, equip-
2 ment, personnel, information, and facilities of other
3 Federal, State, or local public agencies, with or with-
4 out reimbursement;

5 “(5) in accordance with section 3109 of title 5,
6 United States Code, obtain the assistance and advice
7 of experts and consultants;

8 “(6) accept voluntary and uncompensated serv-
9 ice; and

10 “(7) award grants or enter into cooperative
11 agreements to—

12 “(A) improve the training of investigators
13 in the principles or practice of human partici-
14 pant protections;

15 “(B) enhance the function of Institutional
16 Review Boards; or

17 “(C) otherwise improve human participant
18 protections.

19 “(g) RULE OF CONSTRUCTION.—

20 “(1) EFFECT ON EXISTING LAW.—Effective be-
21 ginning on June 1, 2005, the provisions of part 46
22 (including all subparts) of title 45, Code of Federal
23 Regulations, as amended under subsection (d), shall
24 be construed to supersede such other Federal laws
25 or regulations relating to the protection of human

1 participants in research as may have been in effect
 2 prior to such date.

3 “(2) OFFICE OR ADMINISTRATIVE UNITS.—The
 4 provisions of this section, and sections 491A and
 5 491B, shall allow for, but not be construed as re-
 6 quiring, the termination of any office or other ad-
 7 ministrative unit in a Federal agency that, on the
 8 day before the date of the enactment of the Re-
 9 search Revitalization Act of 2002, had duties relat-
 10 ing to the protection of human participants in re-
 11 search conducted, supported, or otherwise subject to
 12 regulation under Federal law.

13 “(h) AUTHORIZATION OF APPROPRIATIONS.—For the
 14 purposes of carrying out this section, there are authorized
 15 to be appropriated \$20,000,000 for fiscal year 2003, and
 16 such sums as may be necessary for each subsequent fiscal
 17 year.”.

18 **TITLE II—IMPROVING THE EF-**
 19 **FECTIVENESS OF INSTITU-**
 20 **TIONAL REVIEW BOARDS**

21 **SEC. 201. IMPROVING THE EFFECTIVENESS OF INSTITU-**
 22 **TIONAL REVIEW BOARDS.**

23 Part H of title IV of the Public Health Service Act
 24 (42 U.S.C. 289 et seq.) is amended by inserting after sec-
 25 tion 491 the following:

1 **“SEC. 491A. IMPROVING THE EFFECTIVENESS OF INSTITU-**
2 **TIONAL REVIEW BOARDS.**

3 “(a) INSTITUTIONAL REVIEW BOARDS.—Each insti-
4 tution at which covered research is conducted shall estab-
5 lish or enter into a contractual association with a board
6 (to be known as an ‘Institutional Review Board’) or
7 boards under which the board will review covered research
8 conducted or supported by such institution in order to pro-
9 tect the rights of the human participants enrolled in such
10 research.

11 “(b) REQUIREMENT FOR REVIEW.—No investigator
12 shall conduct covered research unless—

13 “(1) such research shall have been reviewed by
14 and recommended for approval by an Institutional
15 Review Board that is established at or contractually
16 associated with the institution at which such covered
17 research is to be conducted, except as provided for
18 in subsection (c); and

19 “(2) with respect to covered research involving
20 greater than minimal risk, policies and practices
21 have been implemented that effectively monitor such
22 research and safeguard against significant dangers
23 to the health and welfare of a human participant or
24 participants due to participation in such research.

25 “(c) ADMINISTRATIVE REVIEW.—

1 “(1) IN GENERAL.—If a proposal to conduct
2 covered research that is submitted for review to an
3 Institutional Review Board conforms to conditions
4 established by the Director under section 491(d)(3),
5 the chair of such Board may select a member or
6 members of such Board to review such proposal in
7 lieu of requiring review by the full Board.

8 “(2) APPROVAL.—A proposal to conduct cov-
9 ered research that is reviewed as provided for in
10 paragraph (1) shall be deemed to be in compliance
11 with the requirements of subsection (b)(1) if such
12 proposal has been approved by the member of the
13 Board selected to review such research.

14 “(d) ACCREDITATION OF INSTITUTIONAL REVIEW
15 BOARDS.—Effective beginning on the date that is 6 years
16 after the date of enactment of this section, no investigator
17 shall conduct covered research unless such research shall
18 have been approved by an Institutional Review Board
19 that—

20 “(1) meets the requirements of subsection (b);
21 and

22 “(2) is accredited—

23 “(A) by the Director for the purposes of
24 reviewing such research pursuant to subsection
25 (e); or

1 “(B) by an accrediting body pursuant to
2 subsection (f).

3 “(e) BASIS FOR ACCREDITATION.—

4 “(1) IN GENERAL.—Not later than 1 year after
5 the date of enactment of this section, the Director,
6 in consultation with the entities described in section
7 491(d)(2), shall by regulation establish standards for
8 the accreditation of Institutional Review Boards.

9 “(2) REQUIREMENTS.—In establishing stand-
10 ards pursuant to paragraph (1), the Director shall
11 require that, to be accredited, an Institutional Re-
12 view Board shall—

13 “(A) have members with sufficient exper-
14 tise or experience to adequately review covered
15 research at the institution or institutions with
16 respect to which the Board is established or
17 contractually associated;

18 “(B) have programs or practices that ade-
19 quately educate members on principles and pro-
20 cedures of human participant protection;

21 “(C) adequately insulate decisions of the
22 Board from improper financial or other con-
23 flicts of interest;

24 “(D) ensure that covered research that is
25 reviewed by such Board is conducted consistent

1 with the ethical principles described in section
2 491(a);

3 “(E) adequately review the process of in-
4 formed consent and, for research involving
5 greater than minimal risk to a human partici-
6 pant or participants, adequately monitor ongo-
7 ing research;

8 “(F) grant waivers only in accordance with
9 section 492B(c); and

10 “(G) conform to such other conditions as
11 may be specified by the Director.

12 “(3) STANDARDS APPLICABLE TO CERTAIN RE-
13 SEARCH.—In establishing standards under para-
14 graph (1), the Director may, by regulation, establish
15 certain additional standards required to be met by—

16 “(A) Boards that review covered research
17 conducted in countries not listed pursuant to
18 subsection (m); or

19 “(B) Cooperative Review Boards, as de-
20 scribed in subsection (l).

21 “(f) ACCREDITING BODY.—

22 “(1) IN GENERAL.—The Director may des-
23 ignate an outside entity or entities (to be known as
24 an ‘accrediting body’) to conduct an accreditation
25 described in subsections (d) and (e), if—

1 “(A) the accrediting body meets standards
2 established by the Director through regulation;
3 and

4 “(B) the Director, based upon an annual
5 evaluation, determines that the performance of
6 the accrediting body is appropriate and accept-
7 able.

8 “(2) WITHDRAWAL OF DESIGNATION.—The Di-
9 rector may at any time withdraw the designation of
10 an entity or entities as an accrediting body if the Di-
11 rector determines that the entity or entities does not
12 meet the standards established pursuant to sub-
13 section (e).

14 “(g) SUSPENSION AND REVOCATION.—The Director
15 may suspend or revoke the accreditation of an Institu-
16 tional Review Board, or impose other restrictions on cov-
17 ered research conducted at the institution with respect to
18 which such Board is established or with which the Board
19 is contractually associated—

20 “(1) after the provision—

21 “(A) of a notice of intent to apply such
22 suspension or revocation by the Director to the
23 chairperson of such Board and to the chief ex-
24 ecutive officer of the institution with respect to

1 which the Board is established or with which
2 the Board is contractually associated; and

3 “(B) of an adequate opportunity for a
4 hearing with respect to the action described in
5 the notice; or

6 “(2) immediately, or at such time as the Direc-
7 tor may determine appropriate, if, in the determina-
8 tion of the Director, there is occurring, or there is
9 likely to imminently occur, significant and unreason-
10 able harm to the health or welfare of a human par-
11 ticipant or human participants involved in research
12 reviewed by such Board.

13 “(h) NOTIFICATION OF INSTITUTIONAL REVIEW
14 BOARD.—

15 “(1) INVESTIGATORS.—In submitting to an In-
16 stitutional Review Board a proposal to conduct cov-
17 ered research, the investigator or investigators con-
18 ducting such research shall notify the Board—

19 “(A) whether such proposal, or a proposal
20 substantially similar to such proposal, has been
21 submitted by such investigator or investigators
22 to any other Institutional Review Board;

23 “(B) as applicable, of the findings of the
24 review made by such other Board, to the extent
25 the findings are available; and

1 “(C) whether such investigators have been
2 disqualified or restricted by any Federal entity
3 in their ability to conduct covered research
4 within the preceding 10 years.

5 “(2) SPONSORS.—

6 “(A) IN GENERAL.—Each sponsor of a
7 proposal to conduct covered research shall no-
8 tify the Institutional Review Board reviewing
9 such research whether such sponsor has been
10 disqualified or restricted by any Federal entity
11 in their ability to conduct covered research
12 within the preceding 10 years.

13 “(B) RULE OF CONSTRUCTION.—For pur-
14 poses of subparagraph (A), a Federal depart-
15 ment or agency shall not be considered a spon-
16 sor of a proposal to conduct covered research.

17 “(3) INSTITUTIONS.—Each institution or insti-
18 tutions at which a project of covered research is pro-
19 posed to be conducted shall notify the Institutional
20 Review Board reviewing such research whether such
21 institution has been disqualified or restricted by any
22 Federal entity in their ability to conduct covered re-
23 search within the preceding 10 years.

24 “(i) ACTIVITIES.—

1 “(1) DATA.—The Director shall collect and
2 maintain data on the number of projects of covered
3 research involving greater than a minimal risk, the
4 number of human participants enrolled in such re-
5 search, the number of waivers granted under section
6 492B(c), and such other information as may, as de-
7 termined by the Director, be necessary to assess the
8 protection of human participants.

9 “(2) REPORT.—The Director shall annually
10 submit reports to the appropriate committees of
11 Congress on the data collected under paragraph (1).

12 “(j) COST RECOVERY.—Institutions may recover
13 costs associated with compliance with human participant
14 protections from sponsors of such research that are Fed-
15 eral agencies as direct costs.

16 “(k) DEMONSTRATION GRANTS.—

17 “(1) IN GENERAL.—The Secretary may award
18 demonstration grants, on a competitive basis, to eli-
19 gible entities to permit such entities to improve, en-
20 hance, or refine the functioning of Institutional Re-
21 view Boards, consistent with the common rule, this
22 section, section 492A, and applicable State and local
23 laws.

24 “(2) ACTIVITIES.—Activities to be supported
25 under grants under paragraph (1) may include—

1 “(A) developing, enhancing, or establishing
2 administrative procedures that facilitate cooper-
3 ative Institutional Review Board review of ap-
4 plications to conduct research on human par-
5 ticipants;

6 “(B) improving coordination and collabora-
7 tion among Institutional Review Boards in the
8 review of research conducted at more than one
9 institution or site; and

10 “(C) other activities that improve the func-
11 tions of Institutional Review Boards, as deter-
12 mined appropriate by the Secretary.

13 “(3) ELIGIBLE ENTITIES.—Entities eligible to
14 receive grants under paragraph (1) shall include
15 hospitals, academic institutions, and other public or
16 private not for profit entities.

17 “(4) AUTHORIZATION OF APPROPRIATIONS.—
18 For carrying out the activities described in this sub-
19 section, there are authorized to be appropriated
20 \$15,000,000 for fiscal year 2003, and such sums as
21 may be necessary for each of fiscal years 2004 and
22 2005.

23 “(1) VOLUNTARY COOPERATIVE REVIEW FOR MULTI-
24 SITE RESEARCH.—

1 “(1) ELECTION OF COOPERATIVE REVIEW.—An
2 Institutional Review Board established at or in con-
3 tractual association with an institution at which
4 multi-site research is proposed to be conducted may,
5 with the consent of the sponsor of such research,
6 voluntarily authorize a Cooperative Review Board to
7 review a proposal to conduct such multi-site re-
8 search.

9 “(2) LIMITATIONS.—An Institutional Review
10 Board entering into a cooperative agreement that is
11 authorized under paragraph (1) shall—

12 “(A) retain final authority to approve or
13 reject a proposal to conduct covered research at
14 the institution at which such Board is estab-
15 lished, or with which such Board is contrac-
16 tually associated;

17 “(B) not amend, or cause to be amended,
18 a proposal to conduct multi-site research that
19 has been approved by a Cooperative Review
20 Board established under paragraph (6) unless
21 such amendments are required to comply with
22 State or local law; and

23 “(C) conduct such activities as are re-
24 quired to monitor and ensure the safety of cov-
25 ered research that is reviewed by such Board

1 and conducted at the institution at which such
2 Board is established or with which such Board
3 is contractually associated.

4 “(3) RESEARCH DEEMED TO MEET REQUIRE-
5 MENTS.—Multi-site research shall be deemed to
6 meet the requirement for review established under
7 subsection (b)(1) if such research is recommended
8 for approval by a majority of the members of a Co-
9 operative Review Board.

10 “(4) DEFINITION.—In this section, the term
11 ‘Cooperative Review Board’ means an Institutional
12 Review Board that reviews covered research that is
13 conducted at more than one institution and that
14 conforms to such conditions as the Director may by
15 regulation specify in accordance with subsection
16 (e)(3).

17 “(5) ADDITIONAL BOARDS ESTABLISHED BY
18 SECRETARY.—The Secretary shall establish one or
19 more Cooperative Review Boards in accordance with
20 this subsection and with such regulations as may be
21 promulgated by the Director under subsection
22 (e)(3).

23 “(m) FEDERALLY SPONSORED OR REGULATED RE-
24 SEARCH CONDUCT OVERSEAS.—

1 “(1) IN GENERAL.—Not later than 1 year after
2 the date of enactment of the Research Revitalization
3 Act of 2002, and every 5 years thereafter, the Direc-
4 tor, in consultation with the Secretary of State, shall
5 determine and publish a list of those foreign coun-
6 tries in which protections for human research par-
7 ticipants are substantially equivalent to those of the
8 United States.

9 “(2) REQUIREMENT FOR REVIEW.—

10 “(A) COUNTRIES ON THE LIST.—Effective
11 beginning on the date that is 3 years after the
12 date of enactment of the Research Revitaliza-
13 tion Act of 2002, no investigator shall conduct
14 research described in section 492B(h)(2)(A) or
15 492B(h)(2)(B) in a country listed by the Direc-
16 tor pursuant to paragraph (1) unless a proposal
17 to conduct such research shall have been sub-
18 mitted to and approved by an ethics review
19 board authorized to review such research in the
20 country in which it is to be conducted.

21 “(B) COUNTRIES NOT ON THE LIST.—Ef-
22 fective beginning on the date that is 3 years
23 after the date of enactment of the Research Re-
24 vitalization Act of 2002, no investigator shall
25 conduct research described in section

1 492B(h)(2)(A) or 492B(h)(2)(B) involving
2 greater than minimal risk in a country not list-
3 ed by the Director pursuant to paragraph (1)
4 unless a proposal to conduct such research shall
5 have been submitted to and approved by—

6 “(i) an ethics review committee au-
7 thorized to review such research in the
8 country in which it is to be conducted, if
9 such a committee exists; and

10 “(ii) an Institutional Review Board
11 that—

12 “(I) has been accredited to re-
13 view covered research, pursuant to
14 subsection (d); and

15 “(II) conforms to such other con-
16 ditions as the Director may establish
17 by regulation under subsection
18 (b)(3)(A).

19 “(n) DATA AND SAFETY MONITORING BOARD.—

20 “(1) IN GENERAL.—The Director may by regu-
21 lation require the establishment of a Data and Safe-
22 ty Monitoring Board (or an equivalent committee) to
23 provide enhanced oversight for areas of research
24 that, in the determination of the Director—

1 “(A) involve novel techniques, methods, or
2 materials;

3 “(B) pose special concerns to the health or
4 welfare of human participants enrolled in such
5 research; and

6 “(C) involve greater than minimal risk to
7 human participants enrolled in such research.

8 “(2) LIMITATIONS.—The limitations on partici-
9 pation applicable to a member of an Institutional
10 Review Board under section 492B(b)(2) shall apply
11 to members of a Data Safety and Monitoring Board
12 (or equivalent committee) established under para-
13 graph (1).”.

14 **SEC. 202. CLERICAL AMENDMENT; RULE OF CONSTRUC-**
15 **TION; SEVERABILITY.**

16 (a) CLERICAL AMENDMENT.—Section 492A(a) of the
17 Public Health Service Act (42 U.S.C. 289a–1(a)(1)) is
18 amended by striking paragraph (1).

19 (b) RULE OF CONSTRUCTION CONCERNING PREEMP-
20 TION.—Nothing in this Act, or an amendment made by
21 this Act, shall be construed to preempt any provision of
22 State law that provides protections to human research
23 subjects that are equal to or greater than the protections
24 provided for in this Act or amendments.

1 (c) SEVERABILITY.—If any provision of this Act, an
 2 amendment made by this Act, or the application of such
 3 provision or amendment to any person or circumstance is
 4 held to be unconstitutional, the remainder of this Act, the
 5 amendments made by this Act, and the application of the
 6 provisions of such to any person or circumstance shall not
 7 be affected thereby.

8 **TITLE III—IMPROVING THE**
 9 **TRAINING OF INVESTIGATORS**

10 **SEC. 301. IMPROVING THE TRAINING OF INVESTIGATORS.**

11 Part H of title IV of the Public Health Service Act
 12 (42 U.S.C. 289 et seq.) is amended by inserting after sec-
 13 tion 491A (as added by section 201) the following:

14 **“SEC. 491B. IMPROVING THE TRAINING OF INVESTIGATORS.**

15 “(a) PAYMENT FOR RECRUITMENT OF PARTICI-
 16 PANTS.—

17 “(1) REGULATIONS.—While recognizing that
 18 payment of human participants may at times be nec-
 19 essary and appropriate, not later than 1 year after
 20 the date of enactment of this section, the Director,
 21 in consultation with the Advisory Committee estab-
 22 lished under section 491A(d) and such Federal offi-
 23 cials as may be necessary, shall promulgate regula-
 24 tions regarding payments for the recruitment or par-
 25 ticipation of human participants in covered research.

1 “(2) REQUIREMENTS OF REGULATIONS.—Regu-
2 lations established under paragraph (1) shall specify
3 the amount of payments or conditions under which
4 such payments may be made that shall be considered
5 by an Institutional Review Board to be incompatible
6 with the principles of section 491(a).

7 “(b) DISCLOSURE IN PUBLICATION.—

8 “(1) IN GENERAL.—Not later than 1 year after
9 the date of enactment of this section, the Secretary
10 shall by regulation require that each applicant for a
11 grant, contract or cooperative agreement which is
12 administered by the Secretary include in its applica-
13 tion or contract proposal assurances satisfactory to
14 the Secretary that such applicant shall, upon publi-
15 cation in a peer-reviewed medium of the results of
16 or a description of the research that is the subject
17 of such application—

18 “(A) disclose to the editors or publishers of
19 such publication whether such applicant holds a
20 significant investment interest in any financially
21 interested entity that is, in whole or in part, the
22 sponsor of such research; and

23 “(B) disclose to the editors or publishers of
24 such publication whether such applicant has re-
25 ceived significant income from any financially

1 interested entity that is in whole or in part the
2 sponsor of such research.

3 “(2) RECOMMENDATION OF CONGRESS.—It is
4 the recommendation of Congress that editors and
5 publishers of peer-reviewed publications in which the
6 results of research conducted by recipients of awards
7 from the Secretary are published should include a
8 description of the information described in subpara-
9 graph (A) and (B) of paragraph (1) with respect to
10 such research when such results are published.

11 “(3) ACTIONS OF THE SECRETARY.—Consistent
12 with existing legal authority, the Secretary shall take
13 action to promote the implementation of the rec-
14 ommendation described in paragraph (2).

15 “(c) PLACEBOS.—

16 “(1) REGULATIONS.—Not later than 1 year
17 after the date of enactment of the Research Revital-
18 ization Act of 2002, the Director shall promulgate
19 regulations regarding the appropriate use of pla-
20 cebos or nontreatment in covered research.

21 “(2) REQUIREMENTS.—In promulgating regula-
22 tions under paragraph (1), the Director shall require
23 that a placebo or nontreatment may not be used in
24 such research if—

1 “(A) another treatment that is available to
2 the investigator and has been shown to be effec-
3 tive could reasonably be provided to a human
4 participant or participants in such research;
5 and

6 “(B) there is risk of significant harm to a
7 human participant or participants in such re-
8 search in the absence of treatment or following
9 administration of a placebo.

10 “(d) AUTHORIZATION OF APPROPRIATIONS.—For the
11 purposes of carrying out this section, there are authorized
12 to be appropriated such sums as may be necessary for fis-
13 cal year 2003 and for each subsequent fiscal year.”.

14 **TITLE IV—FINANCIAL**
15 **CONFLICTS OF INTEREST**

16 **SEC. 401. FINANCIAL CONFLICTS OF INTEREST.**

17 Part H of title IV of the Public Health Service Act
18 (42 U.S.C. 289 et seq.) is amended—

19 (1) by redesignating section 492B as section
20 492D; and

21 (2) by inserting after section 492A, the fol-
22 lowing:

23 **“SEC. 492B. FINANCIAL CONFLICTS OF INTEREST.**

24 “(a) DISCLOSURE OF POTENTIAL FINANCIAL CON-
25 FLICTS OF INTERESTS.—

1 “(1) INVESTIGATORS.—

2 “(A) IN GENERAL.—An investigator sub-
3 mitting to an Institutional Review Board an ap-
4 plication to conduct covered research shall dis-
5 close to such Board—

6 “(i) all significant income received by
7 such investigator from a financially inter-
8 ested entity that is, in whole or in part, the
9 sponsor of such research; and

10 “(ii) all significant investment inter-
11 ests owned or controlled by such investi-
12 gator, in a financially interested entity that
13 is, in whole or in part, the sponsor of such
14 research.

15 “(B) OPTIONAL ROLE OF CONFLICT OF IN-
16 TEREST COMMITTEE.—An Institutional Review
17 Board may deem an investigator to have com-
18 plied with the requirements of subparagraph
19 (A) if such investigator shall have submitted
20 the information described in such subparagraph
21 to a conflict of interest committee that is estab-
22 lished at the institution with respect to which
23 the Institutional Review Board is established or
24 associated, so long as the conflict of interest
25 committee provides a summary of such informa-

1 tion to such Institutional Review Board, includ-
2 ing a determination based on such information
3 as to whether a significant income or a signifi-
4 cant investment interest exists.

5 “(2) BOARD MEMBERS.—

6 “(A) IN GENERAL.—A member of an Insti-
7 tutional Review Board shall disclose to such
8 Board—

9 “(i) all significant income received by
10 such member from a financially interested
11 entity that is, in whole or in part, the
12 sponsor of any covered research reviewed
13 by such Board; and

14 “(ii) all significant investment inter-
15 ests owned or controlled by such member,
16 in a financially interested entity that is, in
17 whole or in part, the sponsor of any cov-
18 ered research reviewed by such Board.

19 “(B) OPTIONAL ROLE OF CONFLICT OF IN-
20 TEREST COMMITTEE.—An Institutional Review
21 Board may deem a board member to have com-
22 plied with the requirements of subparagraph
23 (A) if such member shall have submitted the in-
24 formation described in such subparagraph to a
25 conflict of interest committee that is established

1 at the institution with respect to which the In-
2 stitutional Review Board is established or asso-
3 ciated, so long as the conflict of interest com-
4 mittee provides a summary of such information
5 to such Institutional Review Board, including a
6 determination based on such information as to
7 whether a significant income or a significant in-
8 vestment interest exists.

9 “(3) UPDATED INFORMATION.—If the informa-
10 tion described in paragraphs (1) or (2) with respect
11 to an investigator or Board member substantially
12 changes subsequent to the date on which such infor-
13 mation is submitted to the Institutional Review
14 Board as described in either such paragraph, or to
15 a conflict of interest committee, such investigator or
16 Board member shall provide such Institutional Re-
17 view Board or conflict of interest committee, as ap-
18 propriate, with a statement describing such changes
19 as soon as practicable following the date of such
20 change.

21 “(b) PROTECTION AGAINST FINANCIAL CONFLICTS
22 OF INTEREST.—

23 “(1) INVESTIGATORS.—Unless an Institutional
24 Review Board determines that the compelling cir-
25 cumstances described in subsection (c) exist, such

1 Institutional Review Board shall not approve, and an
2 investigator shall not conduct, covered research in-
3 volving greater than minimal risk if, based on infor-
4 mation provided under subsection (a)(1)(A) or based
5 on a summary of such information provided by a
6 conflict of interest committee under subsection
7 (a)(1)(B), or based on other reasonable criteria,
8 such Institutional Review Board determines that an
9 investigator directly participating in such research—

10 “(A) owns or controls a significant invest-
11 ment interest in a financially interested entity
12 that is in whole or in part, the sponsor of such
13 research; or

14 “(B) receives significant income from a fi-
15 nancially interested entity that is, in whole or
16 in part, the sponsor of such research.

17 “(2) BOARD MEMBERS.—A member of an Insti-
18 tutional Review Board shall not participate in the
19 review of covered research involving greater than
20 minimal risk if, based on information provided under
21 subsection (a)(2)(A) or based on a summary of such
22 information provided by a conflict of interest com-
23 mittee under subsection (a)(2)(B), or based on other
24 reasonable criteria, such Institutional Review Board
25 determines that the Board member—

1 “(A) owns or controls a significant invest-
2 ment interest in a financially interested entity
3 that is in whole or in part, the sponsor of such
4 research; or

5 “(B) receives significant income from a fi-
6 nancially interested entity that is, in whole or
7 in part, the sponsor of such research.

8 “(c) COMPELLING CIRCUMSTANCES.—

9 “(1) IN GENERAL.—An Institutional Review
10 Board may waive the requirements of subsection
11 (b)(1) with respect to an investigator proposing to
12 conduct covered research, and an investigator may
13 conduct such research, if such Institutional Review
14 Board determines that there exist compelling cir-
15 cumstances as described in paragraph (2) that jus-
16 tify such a waiver.

17 “(2) DETERMINATIONS.—With respect to an in-
18 vestigator, a waiver may be granted under para-
19 graph (1) only if the Institutional Review Board
20 finds that—

21 “(A) the investigator who is the subject of
22 the waiver is uniquely qualified to conduct such
23 research;

1 “(B) such research could not safely or
2 practicably be conducted in the absence of such
3 waiver;

4 “(C) the significance of such research is
5 sufficient to justify such waiver; and

6 “(D) no human participant in such re-
7 search is reasonably likely to suffer significant
8 or unreasonable harm as a result to the grant-
9 ing of such waiver.

10 “(d) DECLARATION OF FINANCIAL INTERESTS TO
11 RESEARCH PARTICIPANTS.—If an Institutional Review
12 Board grants a waiver under subsection (c) with respect
13 to an investigator conducting a project of covered re-
14 search, such Institutional Review Board shall require that
15 all human participants who are considering enrolling in
16 such research be provided, as part of the informed consent
17 process, with information, in such form as may be deemed
18 appropriate by such Institutional Review Board, that
19 clearly indicates that an investigator directly involved in
20 the conduct of such research—

21 “(1) owns or controls a significant investment
22 interest in a financially interested entity that is in
23 whole or in part, the sponsor of such research; or

1 “(2) receives significant income from a finan-
2 cially interested entity that is, in whole or in part,
3 the sponsor of such research.

4 “(e) ADDITIONAL SAFEGUARDS.—If an Institutional
5 Review Board grants a waiver under subsection (c) with
6 respect to an investigator conducting a project of covered
7 research, such Institutional Review Board shall require
8 that the investigator or investigators conducting such re-
9 search institute additional measures to safeguard the
10 health and welfare of human participants enrolled in such
11 research. Such measures may include—

12 “(1) audits of the informed consent process;

13 “(2) requirements that a disinterested observer
14 monitor the informed consent process;

15 “(3) the establishment of a data safety moni-
16 toring board;

17 “(4) requirements that an investigator place
18 certain financial interests in escrow prior to the con-
19 duct of such research; or

20 “(5) such other measures as may be determined
21 by such Institutional Review Board to be reasonable
22 and necessary.

23 “(f) RULE OF CONSTRUCTION.—Subsections (a) and
24 (b) shall not be construed to limit the authority of an In-
25 stitutional Review Board to require—

1 “(1) disclosure of income or investment inter-
2 ests other than those described in such subsection;

3 “(2) disclosure of income or investment inter-
4 ests to human participants involved in covered re-
5 search; or

6 “(3) adherence to such other procedures as may
7 be necessary to comply with section 491.

8 “(g) INSTITUTIONAL CONFLICTS OF INTEREST.—
9 Not later than 2 years after the date of enactment of the
10 Research Revitalization Act of 2002, the Director, in col-
11 laboration with the advisory committee described in sec-
12 tion 491(e), and with scientific, medical, and academic
13 professional organizations, shall promulgate regulations to
14 limit improper conflicts of interest that may affect re-
15 search involving human participants that may arise as a
16 result of investments made by educational or other not-
17 for-profit institutions at which covered research is con-
18 ducted in a financially interested entity that is, in whole
19 or in part, the sponsor of such research.

20 “(h) DEFINITIONS.—In this section, and sections
21 491, 491A, 491B, 492B, and 492C:

22 “(1) FINANCIALLY INTERESTED ENTITY.—The
23 term ‘financially interested entity’ means any entity
24 with financial interests that would reasonably appear
25 to be affected by the conduct or outcome of a project

1 of covered research. Such term shall not include any
2 Federal agency.

3 “(2) COVERED RESEARCH.—The term ‘covered
4 research’ means research that is conducted using
5 one or more human participants, and that—

6 “(A) is—

7 “(i) conducted or supported by a Fed-
8 eral agency; and

9 “(ii) not described in subsection
10 101(b) of part 46 of title 45, Code of Fed-
11 eral Regulations (as in effect on the day
12 before the date of enactment of the Re-
13 search Revitalization Act of 2001);

14 “(B) is not described in subparagraph (A),
15 and that—

16 “(i) is otherwise subject to regulation
17 under a provision of Federal law (other
18 than this section), including research that
19 forms part of an investigational new drug
20 under section 505 of the Food, Drug, and
21 Cosmetics Act, a class III device under
22 section 515 of such Act, or a biological
23 product under section 351 of the Public
24 Health Service Act; and

1 “(ii) is not described in subsection
2 101(b) of part 46 of title 45, Code of Fed-
3 eral Regulations (as in effect on the day
4 before the date of enactment of the Re-
5 search Revitalization Act of 2001); or

6 “(C) is not described in subparagraph (A)
7 or (B), and that—

8 “(i) has activities that are in or that
9 affect interstate commerce;

10 “(ii) is not described in subsection
11 101(b) of part 46 of title 45, Code of Fed-
12 eral Regulations (as in effect on the day
13 before the date of enactment of the Re-
14 search Revitalization Act of 2002); and

15 “(iii) is conducted within the United
16 States, its territories or possessions.

17 “(3) COMMON RULE.—The term ‘common rule’
18 means the policy for the protection of human re-
19 search subjects as contained in part 46 of title 45,
20 Code of Federal Regulations (including all subparts
21 thereto).

22 “(4) DIRECTOR.—The term ‘Director’ means
23 the Director of the Office of Human Participant
24 Protections (as established by section 491(b)).

1 “(5) FEDERAL AGENCY.—The term ‘Federal
2 agency’ has the meaning given the term ‘Executive
3 agency’ in section 105 of title 5, United States Code.

4 “(6) HUMAN PARTICIPANT.—The term ‘human
5 participant’ has the meaning given the term ‘human
6 subject’ under section 102(f) of part 46 of title 45,
7 Code of Federal Regulations, as in effect on the day
8 before the date of enactment of the Research Revi-
9 talization Act of 2002.

10 “(7) INFORMED CONSENT.—The term ‘in-
11 formed consent’ means the process of requesting the
12 voluntary agreement of an individual, based on ade-
13 quate knowledge and understanding of relevant ma-
14 terial available at the time of such agreement, to
15 participate in covered research.

16 “(8) MINIMAL RISK.—The term ‘minimal risk’
17 means the probability and magnitude of physical or
18 psychological harm that is normally encountered in
19 daily life, or in routine medical, dental, or psycho-
20 logical examinations.

21 “(9) RESEARCH.—The term ‘research’ means a
22 systematic investigation designed to develop or con-
23 tribute to generalizable knowledge.

24 “(10) SECRETARY.—The term ‘the Secretary’
25 means the Secretary of Health and Human Services.

1 “(11) SIGNIFICANT INCOME.—

2 “(A) IN GENERAL.—The term ‘significant
3 income’ means the receipt by an individual, or
4 the right or expectation, based on contractual
5 arrangement, to receive, any income from a fi-
6 nancially interested entity (or from an agent or
7 other representative thereof), whether in the
8 form of a fee, salary, allowance, forbearance,
9 forgiveness, interest in real or personal prop-
10 erty, dividend, royalty derived from the licens-
11 ing of technology, rent, capital gain, real or per-
12 sonal property, or any other form of compensa-
13 tion, or any combination thereof, so long as
14 such income received from any one financially
15 interested entity, when aggregated for an indi-
16 vidual and that individual’s spouse and depend-
17 ent children over the next 12 months, is ex-
18 pected to exceed \$10,000, or the dollar amount
19 determined by the Director under paragraph
20 (12)(C).

21 “(B) LIMITATION.—Such term shall not
22 include any income received from a financially
23 interested entity that is the principal employer
24 of such individual.

25 “(12) SIGNIFICANT INVESTMENT INTEREST.—

1 “(A) IN GENERAL.—The term ‘significant
2 investment interest’ means any stock, stock op-
3 tion, or similar ownership interest by an indi-
4 vidual in any financially interested entity, the
5 value of which, when aggregated for an indi-
6 vidual and that individual’s spouse and depend-
7 ent children—

8 “(i) exceeds \$10,000 or the dollar
9 amount determined by the Director under
10 subparagraph (C), as determined through
11 reference to public prices or other reason-
12 able measures of fair market value; or

13 “(ii) represents more than a 5 percent
14 ownership interest in any single financially
15 interested entity.

16 “(B) LIMITATION.—Such term shall not
17 include—

18 “(i) any interest in a financially inter-
19 ested entity that arises solely by reason of
20 an investment by a mutual, pension, or
21 other institutional investment fund over
22 which the individual involved does not ex-
23 ercise control; and

1 “(ii) any interest in a financially in-
2 terested entity that is the principal em-
3 ployer of such individual.

4 “(13) ADJUSTMENT OF AMOUNTS.—The Direc-
5 tor shall increase the amounts described in para-
6 graphs (11) and (12)(A)(i) for each fiscal year to re-
7 flect the percentage increase, if any, in the Con-
8 sumer Price Index for all urban consumers for the
9 previous fiscal year.”.

10 **TITLE V—VIOLATIONS OF ETH-**
11 **ICAL STANDARDS FOR PRO-**
12 **TECTING HUMAN PARTICI-**
13 **PANTS**

14 **SEC. 501. VIOLATIONS OF ETHICAL STANDARDS FOR PRO-**
15 **TECTING HUMAN PARTICIPANTS.**

16 Part H of title IV of the Public Health Service Act
17 (42 U.S.C. 289 et seq.) is amended by inserting after sec-
18 tion 492B (as added by section 401) the following:

19 **“SEC. 492C. ENFORCEMENT.**

20 “(a) INJUNCTIONS.—

21 “(1) IN GENERAL.—If the Secretary has reason
22 to believe, upon the recommendation of the Director
23 or upon any other reasonable basis, that the con-
24 tinuation of any activity by an investigator, a spon-
25 sor, or an Institutional Review Board would cause

1 significant and unreasonable harm to the health or
2 welfare of a human participant enrolled in covered
3 research, the Secretary may bring an action in the
4 district court of the United States for the district in
5 which such covered research is being conducted or in
6 which an Institutional Review Board that reviews
7 such research is located to enjoin the continuation of
8 such research.

9 “(2) TEMPORARY ORDER.—Upon a proper
10 showing in an action under paragraph (1), a tem-
11 porary injunction or restraining order against the
12 continuation of the research involved, pending the
13 issuance of a final order under this subsection, shall
14 be granted without bond by the district court.

15 “(b) JUDICIAL REVIEW.—

16 “(1) IN GENERAL.—Any investigator, sponsor,
17 or Institutional Review Board that is the subject of
18 an injunction under subsection (a) may, at any time
19 during the 60-day period beginning on the date on
20 which the injunction becomes final, file a petition
21 with the appropriate United States Court of Appeals
22 for judicial review of such injunction.

23 “(2) ACTION.—As soon as practicable after re-
24 ceipt of a petition under paragraph (1), the clerk of
25 the court shall transmit a copy of the petition to the

1 Secretary or other officer designated by the Sec-
2 retary for that purpose. As soon as practicable after
3 receipt such copy, the Secretary shall transmit a
4 copy of the petition to the Secretary or other officer
5 designated by the Secretary for that purpose. As
6 soon as practicable after receipt of such copy, the
7 Secretary shall file in the court the record on which
8 the action of the Secretary is based, as provided for
9 in section 2112 of title 28, United States Code.

10 “(3) ADDITIONAL EVIDENCE.—If a petitioner
11 under paragraph (1) applies to the court for leave to
12 produce additional evidence, and demonstrates to the
13 satisfaction of the court that such additional evi-
14 dence is material and that there were reasonable
15 grounds for the failure to produce such evidence in
16 the proceeding before the Secretary, the court may
17 order such additional evidence (and evidence in re-
18 buttal of such additional evidence) to be taken be-
19 fore the Secretary, and to be produced upon the
20 hearing in such manner and upon such terms and
21 conditions as the court may deem proper. The Sec-
22 retary may modify the findings of the Secretary as
23 to the facts, or make new findings, by reason of the
24 additional evidence so taken, and the Secretary shall
25 file such modified or new findings, and the rec-

1 ommendations of the Secretary, if any, for the modi-
2 fication or setting aside of the original action of the
3 Secretary, with the return of such additional evi-
4 dence.

5 “(4) JUDGMENT OF COURT.—Upon the filing of
6 a petition under paragraph (1), the court shall have
7 jurisdiction to affirm the action that is the subject
8 of the petition, or to set such action aside in whole
9 or in part, temporarily or permanently. The findings
10 of the Secretary as to the facts, if supported by sub-
11 stantial evidence, shall be conclusive.

12 “(5) FINALITY OF JUDGMENT.—The judgment
13 of the court affirming or setting aside, in whole or
14 in part, an action of the Secretary that is the sub-
15 ject of a petition under paragraph (1) shall be final,
16 subject to review by the Supreme Court of the
17 United States upon certiorari or certification as pro-
18 vided for in section 1254 of title 28, United States
19 Code.

20 “(c) PLANS FOR CORRECTION OF VIOLATIONS.—If
21 the Secretary determines that an investigator or sponsor
22 conducting covered research, or an Institutional Review
23 Board reviewing covered research, has substantially vio-
24 lated the provisions of sections 491, 491A, or 491B, or
25 regulations promulgated under such sections, the Sec-

1 retary may require directed plans of correction in lieu of
2 commencing an action under subsection (a).

3 “(d) WHISTLEBLOWER PROTECTION.—It shall be un-
4 lawful for any individual to knowingly terminate the em-
5 ployment of, or otherwise discipline, an employee because
6 such employee has reported a violation of any requirement
7 of section 491, 491A, 491B, 492B, or 492C, or any regu-
8 lation promulgated under such sections, to the Secretary
9 or the Attorney General (or to any individual acting on
10 behalf of the Secretary or the Attorney General).

11 “(e) SANCTIONS FOR SUBSTANTIAL AND INTEN-
12 TIONAL VIOLATIONS.—Whoever substantially and inten-
13 tionally violates any requirement of subsection (d) or sec-
14 tion 491, 491A, 491B, 492B, or 492C, or any regulation
15 promulgated under such subsection or sections, shall be
16 subject to a civil penalty in an amount that is appropriate
17 for the violation involved, but not to exceed \$250,000.”.

○