107TH CONGRESS
2D 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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Research Revitalization Act of 2002''.

SEC. 2. FINDINGS AND PURPOSES.

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

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

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

(2) In response to findings of intolerable ethical abuses of human subjects in research sponsored by the Public Health Service and other Federal agencies, Congress enacted the National Research Act (Public Law 93–348) to provide ethical protections for human subjects in Federally sponsored research and to create the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

(3) The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued the Belmont Report, which stated that the treatment of human subjects in research should be based on the principles of respect for persons, beneficence, and justice.

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

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

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

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

(7) No provision of United States law explicitly requires that informed consent and independent review of all research involving human participants be obtained.

(8) Numerous experts report and reviews have found that the current system of protections for human participants needs to be revitalized and enhanced to keep pace with the changing nature of research.

(9) In 1995, the President's Advisory Committee on Human Radiation Experiments found that there are significant deficiencies in some aspects of the current system for the protection of human participants. In particular, the Committee found that

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

(10) In 1998 and 2000, the Department of Health and Human Services's Inspector General found that the effectiveness of the Institutional Review Board system was ''in jeopardy'' and attention needed to be directed to enhancing human participant protections for a widening scope of clinical investigation.

(11) The Inspector General found that Institutional Review Boards ''review too much, too quickly, with too little expertise''.

(12) In its report on research conducted within the United States, the National Bioethics Advisory Commission recommended significant revisions to the current oversight structure for the protection of research participants. Among other recommendations, the Commission recommended establishing a central office for Federal policy on research participant protections, enacting legislation to ensure that all human participants are covered by ethical protections regardless of the funding source that supports the research, as well as new policies to revitalize Institutional Review Boards.

(13) In its report on international research, the National Bioethics Advisory Commission found that investigators have special responsibilities when conducting research on participants from economically less developed communities. These responsibilities include the need to ensure adequately the provision of informed consent in diverse communities and the consideration of whether participants will benefit from the results of such research when it is concluded.

(14) In light of this and other evidence, legislation is required to enhance the current system for protecting research participants so that—

(A) the safety and wellbeing of human participants is properly safeguarded; and

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

(15)(A) Entities conducting and sponsoring research involving human participants engage in and affect interstate commerce.

(B) Information obtained through research involving human participants affects products and services that move in interstate commerce.

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

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

(E) Sponsors of research involving human participants buy and sell products and services in an interstate market.

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

(1) to provide a comprehensive set of protections for human participants in research;

(2) to promote more effective oversight of research involving human participants;

(3) to prevent improper financial conflicts of interest by those conducting or providing for the ethical oversight of research; and

(4) to provide effective oversight of research involving human participants that is conducted outside the borders of the United States, but is otherwise subject to the regulatory authority of the United States.

TITLE I—HUMAN PARTICIPANT PROTECTIONS

SEC. 101. CONSISTENT NATIONAL APPLICABILITY OF STANDARDS TO PROTECT HUMAN PARTICIPANT IN RESEARCH, ESTABLISHMENT OF A NATIONAL OFFICE OF HUMAN RESEARCH PROTECTIONS.

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

"SEC. 491. CONSISTENT NATIONAL APPLICABILITY OF STANDARDS TO PROTECT HUMAN PARTICIPANT IN RESEARCH, ESTABLISHMENT OF A NATIONAL OFFICE OF HUMAN RESEARCH PROTECTIONS.

''(a) ETHICAL PRINCIPLES FOR THE CONDUCT OF RESEARCH INVOLVING HUMAN PARTICIPANTS.—It is the policy of Congress that all research involving human subjects (that is conducted in the United States, funded by the United States Government, or that is subject to Federal regulatory review) should be conducted so as to ensure that—

''(1) the foreseeable risks have been weighed against the anticipated benefits and the risks are determined to be reasonable and justified by the potential benefits that may result;

''(2) the rights and welfare of the participant, including privacy and the protection of the data concerning such participant, are safeguarded;

''(3) in the case of research that involves more than minimal risk to a human participant or participants enrolled in such research, there is a reasonable likelihood that the populations in which the covered research is conducted will benefit from the results of the research;

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

''(5) informed consent in the appropriate manner has been obtained;

''(6) situations that may render a participant vulnerable to harm or coercion are identified and minimized; and

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

''(b) CONSISTENT NATIONAL APPLICABILITY OF STANDARDS TO PROTECT HUMAN PARTICIPANTS IN RESEARCH.—Effective beginning on June 1, 2005, no cov-

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

''(1) the provisions of part 46 (including all subparts) of title 45, Code of Federal Regulations (referred to in this part as 'the common rule'), as in effect on June 1, 2003; and

''(2) any amendments to such provisions under subsection (d).

''(c) OFFICE OF HUMAN RESEARCH PROTECTIONS.—

''(1) ESTABLISHMENT.—There is established within the Department of Health and Human Services an office to be known as the Office of Human Research Protections (in this section referred to as the 'Office').

''(2) DIRECTOR.—The Office shall be headed by a Director who shall be appointed by the Secretary, with the advice and consent of the Senate including submission of the nomination to the Committee on Health, Education, Labor, and Pensions of the Senate for appropriate hearings. The term of office of the Director shall be 6 years, except that the Secretary may remove a Director who fails to carry out the duties of the Director in good conduct. An individual may be appointed to the office of Director for no more than 2 terms.

''(d) AMENDMENTS TO THE COMMON RULE.—

''(1) IN GENERAL.—The Director may by regulation amend the provisions of the common rule, except to the extent that any such amendment is in conflict with this section or any of sections 491A, 491B, 492B, and 492C.

''(2) CONSULTATIONS.—In promulgating regulations under paragraph (1), the Director shall, to the maximum extent practicable, consult with—

''(A) the Advisory Committee under subsection (e); and

''(B) the Human Subjects Research Subcommittee of the National Science and Technology Council (or any successor to such Subcommittee) to the extent that such subcommittee is conducting business or meetings.

''(3) AUTHORITY FOR DETERMINATIONS.—The Director may promulgate regulations under this subsection regarding—

''(A) whether research is covered research under the meaning given that term under section 492B(h)(2); and

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

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

''(4) CONGRESSIONAL FINDINGS.—

''(A) FINDING REGARDING RESEARCH THAT INVOLVES LESS THAN MINIMAL RISK.—Congress finds that much—

''(i) social science research; and

''(ii) other research that does not involve—

''(I) the introduction of foreign substances into the body of a human participant or participants;

''(II) significant alterations of the physical or sensory environment of a human participant or participants; or

''(III) significant risks to the privacy, dignity, or economic wellbeing of a human participant or participants;

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

''(B) FINDING REGARDING RESEARCH INVOLVING INDIVIDUALS WHO HAVE UNDERGONE TRAUMA.—Congress finds that—

''(i) in circumstances in which an individual has undergone trauma, research involving the individual often cannot practically be carried out with the consent of the individual; and

''(ii) in such limited circumstances, there are acceptable alternative means of obtaining consent, as described in section 50.24 of title 21, Code of Federal Regulations (as in effect on the day before the date of enactment of the Research Revitalization Act of 2001).

''(5) RECOGNITION OF FINDING.—The Director shall consider—

''(A) the finding under paragraph (4)(A) in promulgating regulations under paragraph (3)(B); and

''(B) the finding under paragraph (4)(B) in promulgating regulations regarding informed consent under paragraph (1).

''(e) ADVISORY COMMITTEE.—The Secretary shall establish a National Human Research Protections Advisory Committee to serve as an Advisory Committee for purposes of providing expert advice and counsel to the Sec-

retary on issues relating to or associated with the protection of human research participants.

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

''(1) appoint and fix the compensation of officers and employees for the Office in accordance with chapter 51 of title 5, United States Code, and subchapter III of chapter 53 of such title;

''(2) acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Administrator of General Services, buildings or portions of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed 10 years;

''(3) enter into contracts, subject to the availability of amounts made available in appropriations Acts, including contracts for financial and administrative services (such as budget and accounting, financial reporting, personnel, and procurement), with the General Services Administration, or such other Federal agencies as the Director of the Office determines to be appropriate;

''(4) use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement;

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

''(6) accept voluntary and uncompensated service; and

''(7) award grants or enter into cooperative agreements to—

''(A) improve the training of investigators in the principles or practice of human participant protections;

''(B) enhance the function of Institutional Review Boards; or

''(C) otherwise improve human participant protections.

''(g) RULE OF CONSTRUCTION.—

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

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

''(2) OFFICE OR ADMINISTRATIVE UNITS.—The provisions of this section, and sections 491A and 491B, shall allow for, but not be construed as requiring, the termination of any office or other administrative unit in a Federal agency that, on the day before the date of the enactment of the Research Revitalization Act of 2002, had duties relating to the protection of human participants in research conducted, supported, or otherwise subject to regulation under Federal law.

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

TITLE II—IMPROVING THE EFFECTIVENESS OF INSTITUTIONAL REVIEW BOARDS

SEC. 201. IMPROVING THE EFFECTIVENESS OF INSTITUTIONAL REVIEW BOARDS.

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

"SEC. 491A. IMPROVING THE EFFECTIVENESS OF INSTITUTIONAL REVIEW BOARDS.

"(a) INSTITUTIONAL REVIEW BOARDS.—Each institution at which covered research is conducted shall establish or enter into a contractual association with a board (to be known as an 'Institutional Review Board') or boards under which the board will review covered research conducted or supported by such institution in order to protect the rights of the human participants enrolled in such research.

"(b) REQUIREMENT FOR REVIEW.—No investigator shall conduct covered research unless—

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

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

"(c) ADMINISTRATIVE REVIEW.—

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

''(2) APPROVAL.—A proposal to conduct covered research that is reviewed as provided for in paragraph (1) shall be deemed to be in compliance with the requirements of subsection (b)(1) if such proposal has been approved by the member of the Board selected to review such research.

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

''(1) meets the requirements of subsection (b); and

''(2) is accredited—

''(A) by the Director for the purposes of reviewing such research pursuant to subsection (e); or

''(B) by an accrediting body pursuant to subsection (f).

''(e) BASIS FOR ACCREDITATION.—

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

''(2) REQUIREMENTS.—In establishing standards pursuant to paragraph (1), the Director shall require that, to be accredited, an Institutional Review Board shall—

''(A) have members with sufficient expertise or experience to adequately review covered research at the institution or institutions with respect to which the Board is established or contractually associated;

''(B) have programs or practices that adequately educate members on principles and procedures of human participant protection;

''(C) adequately insulate decisions of the Board from improper financial or other conflicts of interest;

''(D) ensure that covered research that is reviewed by such Board is conducted consistent

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

"(E) adequately review the process of informed consent and, for research involving greater than minimal risk to a human participant or participants, adequately monitor ongoing research;

"(F) grant waivers only in accordance with section 492B(c); and

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

"(3) STANDARDS APPLICABLE TO CERTAIN RESEARCH.—In establishing standards under paragraph (1), the Director may, by regulation, establish certain additional standards required to be met by—

"(A) Boards that review covered research conducted in countries not listed pursuant to subsection (m); or

"(B) Cooperative Review Boards, as described in subsection (l).

"(f) ACCREDITING BODY.—

"(1) IN GENERAL.—The Director may designate an outside entity or entities (to be known as an 'accrediting body') to conduct an accreditation described in subsections (d) and (e), if—

''(A) the accrediting body meets standards established by the Director through regulation; and

''(B) the Director, based upon an annual evaluation, determines that the performance of the accrediting body is appropriate and acceptable.

''(2) WITHDRAWAL OF DESIGNATION.—The Director may at any time withdraw the designation of an entity or entities as an accrediting body if the Director determines that the entity or entities does not meet the standards established pursuant to subsection (e).

''(g) SUSPENSION AND REVOCATION.—The Director may suspend or revoke the accreditation of an Institutional Review Board, or impose other restrictions on covered research conducted at the institution with respect to which such Board is established or with which the Board is contractually associated—

''(1) after the provision—

''(A) of a notice of intent to apply such suspension or revocation by the Director to the chairperson of such Board and to the chief executive officer of the institution with respect to

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

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

"(2) immediately, or at such time as the Director may determine appropriate, if, in the determination of the Director, there is occurring, or there is likely to imminently occur, significant and unreasonable harm to the health or welfare of a human participant or human participants involved in research reviewed by such Board.

"(h) NOTIFICATION OF INSTITUTIONAL REVIEW BOARD.—

"(1) INVESTIGATORS.—In submitting to an Institutional Review Board a proposal to conduct covered research, the investigator or investigators conducting such research shall notify the Board—

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

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

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

''(2) SPONSORS.—

''(A) IN GENERAL.—Each sponsor of a proposal to conduct covered research shall notify the Institutional Review Board reviewing such research whether such sponsor has been disqualified or restricted by any Federal entity in their ability to conduct covered research within the preceding 10 years.

''(B) RULE OF CONSTRUCTION.—For purposes of subparagraph (A), a Federal department or agency shall not be considered a sponsor of a proposal to conduct covered research.

''(3) INSTITUTIONS.—Each institution or institutions at which a project of covered research is proposed to be conducted shall notify the Institutional Review Board reviewing such research whether such institution has been disqualified or restricted by any Federal entity in their ability to conduct covered research within the preceding 10 years.

''(i) ACTIVITIES.—

''(1) DATA.—The Director shall collect and maintain data on the number of projects of covered research involving greater than a minimal risk, the number of human participants enrolled in such research, the number of waivers granted under section 492B(c), and such other information as may, as determined by the Director, be necessary to assess the protection of human participants.

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

''(j) COST RECOVERY.—Institutions may recover costs associated with compliance with human participant protections from sponsors of such research that are Federal agencies as direct costs.

''(k) DEMONSTRATION GRANTS.—

''(1) IN GENERAL.—The Secretary may award demonstration grants, on a competitive basis, to eligible entities to permit such entities to improve, enhance, or refine the functioning of Institutional Review Boards, consistent with the common rule, this section, section 492A, and applicable State and local laws.

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

''(A) developing, enhancing, or establishing administrative procedures that facilitate cooperative Institutional Review Board review of applications to conduct research on human participants;

''(B) improving coordination and collaboration among Institutional Review Boards in the review of research conducted at more than one institution or site; and

''(C) other activities that improve the functions of Institutional Review Boards, as determined appropriate by the Secretary.

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

''(4) AUTHORIZATION OF APPROPRIATIONS.—For carrying out the activities described in this subsection, there are authorized to be appropriated $15,000,000 for fiscal year 2003, and such sums as may be necessary for each of fiscal years 2004 and 2005.

''(l) VOLUNTARY COOPERATIVE REVIEW FOR MULTI-SITE RESEARCH.—

''(1) ELECTION OF COOPERATIVE REVIEW.—An Institutional Review Board established at or in contractual association with an institution at which multi-site research is proposed to be conducted may, with the consent of the sponsor of such research, voluntarily authorize a Cooperative Review Board to review a proposal to conduct such multi-site research.

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

''(A) retain final authority to approve or reject a proposal to conduct covered research at the institution at which such Board is established, or with which such Board is contractually associated;

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

''(C) conduct such activities as are required to monitor and ensure the safety of covered research that is reviewed by such Board

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

''(3) RESEARCH DEEMED TO MEET REQUIREMENTS.—Multi-site research shall be deemed to meet the requirement for review established under subsection (b)(1) if such research is recommended for approval by a majority of the members of a Cooperative Review Board.

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

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

''(m) FEDERALLY SPONSORED OR REGULATED RESEARCH CONDUCT OVERSEAS.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Research Revitalization Act of 2002, and every 5 years thereafter, the Director, in consultation with the Secretary of State, shall determine and publish a list of those foreign countries in which protections for human research participants are substantially equivalent to those of the United States.

''(2) REQUIREMENT FOR REVIEW.—

''(A) COUNTRIES ON THE LIST.—Effective beginning on the date that is 3 years after the date of enactment of the Research Revitalization Act of 2002, no investigator shall conduct research described in section 492B(h)(2)(A) or 492B(h)(2)(B) in a country listed by the Director pursuant to paragraph (1) unless a proposal to conduct such research shall have been submitted to and approved by an ethics review board authorized to review such research in the country in which it is to be conducted.

''(B) COUNTRIES NOT ON THE LIST.—Effective beginning on the date that is 3 years after the date of enactment of the Research Revitalization Act of 2002, no investigator shall conduct research described in section

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

''(i) an ethics review committee authorized to review such research in the country in which it is to be conducted, if such a committee exists; and

''(ii) an Institutional Review Board that—

''(I) has been accredited to review covered research, pursuant to subsection (d); and

''(II) conforms to such other conditions as the Director may establish by regulation under subsection (b)(3)(A).

''(n) DATA AND SAFETY MONITORING BOARD.—

''(1) IN GENERAL.—The Director may by regulation require the establishment of a Data and Safety Monitoring Board (or an equivalent committee) to provide enhanced oversight for areas of research that, in the determination of the Director—

"(A) involve novel techniques, methods, or materials;

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

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

"(2) LIMITATIONS.—The limitations on participation applicable to a member of an Institutional Review Board under section 492B(b)(2) shall apply to members of a Data Safety and Monitoring Board (or equivalent committee) established under paragraph (1).".

SEC. 202. CLERICAL AMENDMENT; RULE OF CONSTRUCTION; SEVERABILITY.

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

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

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

TITLE III—IMPROVING THE TRAINING OF INVESTIGATORS

SEC. 301. IMPROVING THE TRAINING OF INVESTIGATORS.

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

"SEC. 491B. IMPROVING THE TRAINING OF INVESTIGATORS.

''(a) PAYMENT FOR RECRUITMENT OF PARTICIPANTS.—

''(1) REGULATIONS.—While recognizing that payment of human participants may at times be necessary and appropriate, not later than 1 year after the date of enactment of this section, the Director, in consultation with the Advisory Committee established under section 491A(d) and such Federal officials as may be necessary, shall promulgate regulations regarding payments for the recruitment or participation of human participants in covered research.

''(2) REQUIREMENTS OF REGULATIONS.—Regulations established under paragraph (1) shall specify the amount of payments or conditions under which such payments may be made that shall be considered by an Institutional Review Board to be incompatible with the principles of section 491(a).

''(b) DISCLOSURE IN PUBLICATION.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary shall by regulation require that each applicant for a grant, contract or cooperative agreement which is administered by the Secretary include in its application or contract proposal assurances satisfactory to the Secretary that such applicant shall, upon publication in a peer-reviewed medium of the results of or a description of the research that is the subject of such application—

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

''(B) disclose to the editors or publishers of such publication whether such applicant has received significant income from any financially

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

''(2) RECOMMENDATION OF CONGRESS.—It is the recommendation of Congress that editors and publishers of peer-reviewed publications in which the results of research conducted by recipients of awards from the Secretary are published should include a description of the information described in subparagraph (A) and (B) of paragraph (1) with respect to such research when such results are published.

''(3) ACTIONS OF THE SECRETARY.—Consistent with existing legal authority, the Secretary shall take action to promote the implementation of the recommendation described in paragraph (2).

''(c) PLACEBOS.—

''(1) REGULATIONS.—Not later than 1 year after the date of enactment of the Research Revitalization Act of 2002, the Director shall promulgate regulations regarding the appropriate use of placebos or nontreatment in covered research.

''(2) REQUIREMENTS.—In promulgating regulations under paragraph (1), the Director shall require that a placebo or nontreatment may not be used in such research if—

''(A) another treatment that is available to the investigator and has been shown to be effective could reasonably be provided to a human participant or participants in such research; and

''(B) there is risk of significant harm to a human participant or participants in such research in the absence of treatment or following administration of a placebo.

''(d) AUTHORIZATION OF APPROPRIATIONS.—For the purposes of carrying out this section, there are authorized to be appropriated such sums as may be necessary for fiscal year 2003 and for each subsequent fiscal year.''.

TITLE IV—FINANCIAL CONFLICTS OF INTEREST

SEC. 401. FINANCIAL CONFLICTS OF INTEREST.

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

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

(2) by inserting after section 492A, the following:

''SEC. 492B. FINANCIAL CONFLICTS OF INTEREST.

''(a) DISCLOSURE OF POTENTIAL FINANCIAL CONFLICTS OF INTERESTS.—

''(1) INVESTIGATORS.—

''(A) IN GENERAL.—An investigator submitting to an Institutional Review Board an application to conduct covered research shall disclose to such Board—

''(i) all significant income received by such investigator from a financially interested entity that is, in whole or in part, the sponsor of such research; and

''(ii) all significant investment interests owned or controlled by such investigator, in a financially interested entity that is, in whole or in part, the sponsor of such research.

''(B) OPTIONAL ROLE OF CONFLICT OF INTEREST COMMITTEE.—An Institutional Review Board may deem an investigator to have complied with the requirements of subparagraph (A) if such investigator shall have submitted the information described in such subparagraph to a conflict of interest committee that is established at the institution with respect to which the Institutional Review Board is established or associated, so long as the conflict of interest committee provides a summary of such informa-

tion to such Institutional Review Board, including a determination based on such information as to whether a significant income or a significant investment interest exists.

''(2) BOARD MEMBERS.—

''(A) IN GENERAL.—A member of an Institutional Review Board shall disclose to such Board—

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

''(ii) all significant investment interests owned or controlled by such member, in a financially interested entity that is, in whole or in part, the sponsor of any covered research reviewed by such Board.

''(B) OPTIONAL ROLE OF CONFLICT OF INTEREST COMMITTEE.—An Institutional Review Board may deem a board member to have complied with the requirements of subparagraph (A) if such member shall have submitted the information described in such subparagraph to a conflict of interest committee that is established

at the institution with respect to which the Institutional Review Board is established or associated, so long as the conflict of interest committee provides a summary of such information to such Institutional Review Board, including a determination based on such information as to whether a significant income or a significant investment interest exists.

''(3) UPDATED INFORMATION.—If the information described in paragraphs (1) or (2) with respect to an investigator or Board member substantially changes subsequent to the date on which such information is submitted to the Institutional Review Board as described in either such paragraph, or to a conflict of interest committee, such investigator or Board member shall provide such Institutional Review Board or conflict of interest committee, as appropriate, with a statement describing such changes as soon as practicable following the date of such change.

''(b) PROTECTION AGAINST FINANCIAL CONFLICTS OF INTEREST.—

''(1) INVESTIGATORS.—Unless an Institutional Review Board determines that the compelling circumstances described in subsection (c) exist, such

Institutional Review Board shall not approve, and an investigator shall not conduct, covered research involving greater than minimal risk if, based on information provided under subsection (a)(1)(A) or based on a summary of such information provided by a conflict of interest committee under subsection (a)(1)(B), or based on other reasonable criteria, such Institutional Review Board determines that an investigator directly participating in such research—

"(A) owns or controls a significant investment interest in a financially interested entity that is in whole or in part, the sponsor of such research; or

"(B) receives significant income from a financially interested entity that is, in whole or in part, the sponsor of such research.

"(2) BOARD MEMBERS.—A member of an Institutional Review Board shall not participate in the review of covered research involving greater than minimal risk if, based on information provided under subsection (a)(2)(A) or based on a summary of such information provided by a conflict of interest committee under subsection (a)(2)(B), or based on other reasonable criteria, such Institutional Review Board determines that the Board member—

''(A) owns or controls a significant investment interest in a financially interested entity that is in whole or in part, the sponsor of such research; or

''(B) receives significant income from a financially interested entity that is, in whole or in part, the sponsor of such research.

''(c) COMPELLING CIRCUMSTANCES.—

''(1) IN GENERAL.—An Institutional Review Board may waive the requirements of subsection (b)(1) with respect to an investigator proposing to conduct covered research, and an investigator may conduct such research, if such Institutional Review Board determines that there exist compelling circumstances as described in paragraph (2) that justify such a waiver.

''(2) DETERMINATIONS.—With respect to an investigator, a waiver may be granted under paragraph (1) only if the Institutional Review Board finds that—

''(A) the investigator who is the subject of the waiver is uniquely qualified to conduct such research;

''(B) such research could not safely or practicably be conducted in the absence of such waiver;

''(C) the significance of such research is sufficient to justify such waiver; and

''(D) no human participant in such research is reasonably likely to suffer significant or unreasonable harm as a result to the granting of such waiver.

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

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

''(2) receives significant income from a financially interested entity that is, in whole or in part, the sponsor of such research.

''(e) ADDITIONAL SAFEGUARDS.—If an Institutional Review Board grants a waiver under subsection (c) with respect to an investigator conducting a project of covered research, such Institutional Review Board shall require that the investigator or investigators conducting such research institute additional measures to safeguard the health and welfare of human participants enrolled in such research. Such measures may include—

''(1) audits of the informed consent process;

''(2) requirements that a disinterested observer monitor the informed consent process;

''(3) the establishment of a data safety monitoring board;

''(4) requirements that an investigator place certain financial interests in escrow prior to the conduct of such research; or

''(5) such other measures as may be determined by such Institutional Review Board to be reasonable and necessary.

''(f) RULE OF CONSTRUCTION.—Subsections (a) and (b) shall not be construed to limit the authority of an Institutional Review Board to require—

''(1) disclosure of income or investment interests other than those described in such subsection;

''(2) disclosure of income or investment interests to human participants involved in covered research; or

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

''(g) INSTITUTIONAL CONFLICTS OF INTEREST.—Not later than 2 years after the date of enactment of the Research Revitalization Act of 2002, the Director, in collaboration with the advisory committee described in section 491(e), and with scientific, medical, and academic professional organizations, shall promulgate regulations to limit improper conflicts of interest that may affect research involving human participants that may arise as a result of investments made by educational or other not-for-profit institutions at which covered research is conducted in a financially interested entity that is, in whole or in part, the sponsor of such research.

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

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

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

''(2) COVERED RESEARCH.—The term 'covered research' means research that is conducted using one or more human participants, and that—

''(A) is—

''(i) conducted or supported by a Federal agency; and

''(ii) not described in subsection 101(b) of part 46 of title 45, Code of Federal Regulations (as in effect on the day before the date of enactment of the Research Revitalization Act of 2001);

''(B) is not described in subparagraph (A), and that—

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

''(ii) is not described in subsection 101(b) of part 46 of title 45, Code of Federal Regulations (as in effect on the day before the date of enactment of the Research Revitalization Act of 2001); or

''(C) is not described in subparagraph (A) or (B), and that—

''(i) has activities that are in or that affect interstate commerce;

''(ii) is not described in subsection 101(b) of part 46 of title 45, Code of Federal Regulations (as in effect on the day before the date of enactment of the Research Revitalization Act of 2002); and

''(iii) is conducted within the United States, its territories or possessions.

''(3) COMMON RULE.—The term 'common rule' means the policy for the protection of human research subjects as contained in part 46 of title 45, Code of Federal Regulations (including all subparts thereto).

''(4) DIRECTOR.—The term 'Director' means the Director of the Office of Human Participant Protections (as established by section 491(b).

''(5) FEDERAL AGENCY.—The term 'Federal agency' has the meaning given the term 'Executive agency' in section 105 of title 5, United States Code.

''(6) HUMAN PARTICIPANT.—The term 'human participant' has the meaning given the term 'human subject' under section 102(f) of part 46 of title 45, Code of Federal Regulations, as in effect on the day before the date of enactment of the Research Revitalization Act of 2002.

''(7) INFORMED CONSENT.—The term 'informed consent' means the process of requesting the voluntary agreement of an individual, based on adequate knowledge and understanding of relevant material available at the time of such agreement, to participate in covered research.

''(8) MINIMAL RISK.—The term 'minimal risk' means the probability and magnitude of physical or psychological harm that is normally encountered in daily life, or in routine medical, dental, or psychological examinations.

''(9) RESEARCH.—The term 'research' means a systematic investigation designed to develop or contribute to generalizable knowledge.

''(10) SECRETARY.—The term 'the Secretary' means the Secretary of Health and Human Services.

''(11) SIGNIFICANT INCOME.—

''(A) IN GENERAL.—The term 'significant income' means the receipt by an individual, or the right or expectation, based on contractual arrangement, to receive, any income from a financially interested entity (or from an agent or other representative thereof), whether in the form of a fee, salary, allowance, forbearance, forgiveness, interest in real or personal property, dividend, royalty derived from the licensing of technology, rent, capital gain, real or personal property, or any other form of compensation, or any combination thereof, so long as such income received from any one financially interested entity, when aggregated for an individual and that individual's spouse and dependent children over the next 12 months, is expected to exceed $10,000, or the dollar amount determined by the Director under paragraph (12)(C).

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

''(12) SIGNIFICANT INVESTMENT INTEREST.—

"(A) IN GENERAL.—The term 'significant investment interest' means any stock, stock option, or similar ownership interest by an individual in any financially interested entity, the value of which, when aggregated for an individual and that individual's spouse and dependent children—

"(i) exceeds $10,000 or the dollar amount determined by the Director under subparagraph (C), as determined through reference to public prices or other reasonable measures of fair market value; or

"(ii) represents more than a 5 percent ownership interest in any single financially interested entity.

"(B) LIMITATION.—Such term shall not include—

"(i) any interest in a financially interested entity that arises solely by reason of an investment by a mutual, pension, or other institutional investment fund over which the individual involved does not exercise control; and

''(ii) any interest in a financially interested entity that is the principal employer of such individual.

''(13) ADJUSTMENT OF AMOUNTS.—The Director shall increase the amounts described in paragraphs (11) and (12)(A)(i) for each fiscal year to reflect the percentage increase, if any, in the Consumer Price Index for all urban consumers for the previous fiscal year.''.

TITLE V—VIOLATIONS OF ETHICAL STANDARDS FOR PROTECTING HUMAN PARTICIPANTS

SEC. 501. VIOLATIONS OF ETHICAL STANDARDS FOR PROTECTING HUMAN PARTICIPANTS.

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

''SEC. 492C. ENFORCEMENT.

''(a) INJUNCTIONS.—

''(1) IN GENERAL.—If the Secretary has reason to believe, upon the recommendation of the Director or upon any other reasonable basis, that the continuation of any activity by an investigator, a sponsor, or an Institutional Review Board would cause

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

''(2) TEMPORARY ORDER.—Upon a proper showing in an action under paragraph (1), a temporary injunction or restraining order against the continuation of the research involved, pending the issuance of a final order under this subsection, shall be granted without bond by the district court.

''(b) JUDICIAL REVIEW.—

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

''(2) ACTION.—As soon as practicable after receipt of a petition under paragraph (1), the clerk of the court shall transmit a copy of the petition to the

Secretary or other officer designated by the Secretary for that purpose. As soon as practicable after receipt such copy, the Secretary shall transmit a copy of the petition to the Secretary or other officer designated by the Secretary for that purpose. As soon as practicable after receipt of such copy, the Secretary shall file in the court the record on which the action of the Secretary is based, as provided for in section 2112 of title 28, United States Code.

''(3) ADDITIONAL EVIDENCE.—If a petitioner under paragraph (1) applies to the court for leave to produce additional evidence, and demonstrates to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to produce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal of such additional evidence) to be taken before the Secretary, and to be produced upon the hearing in such manner and upon such terms and conditions as the court may deem proper. The Secretary may modify the findings of the Secretary as to the facts, or make new findings, by reason of the additional evidence so taken, and the Secretary shall file such modified or new findings, and the rec-

ommendations of the Secretary, if any, for the modification or setting aside of the original action of the Secretary, with the return of such additional evidence.

''(4) JUDGMENT OF COURT.—Upon the filing of a petition under paragraph (1), the court shall have jurisdiction to affirm the action that is the subject of the petition, or to set such action aside in whole or in part, temporarily or permanently. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

''(5) FINALITY OF JUDGMENT.—The judgment of the court affirming or setting aside, in whole or in part, an action of the Secretary that is the subject of a petition under paragraph (1) shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided for in section 1254 of title 28, United States Code.

''(c) PLANS FOR CORRECTION OF VIOLATIONS.—If the Secretary determines that an investigator or sponsor conducting covered research, or an Institutional Review Board reviewing covered research, has substantially violated the provisions of sections 491, 491A, or 491B, or regulations promulgated under such sections, the Sec-

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

''(d) WHISTLEBLOWER PROTECTION.—It shall be unlawful for any individual to knowingly terminate the employment of, or otherwise discipline, an employee because such employee has reported a violation of any requirement of section 491, 491A, 491B, 492B, or 492C, or any regulation promulgated under such sections, to the Secretary or the Attorney General (or to any individual acting on behalf of the Secretary or the Attorney General).

''(e) SANCTIONS FOR SUBSTANTIAL AND INTENTIONAL VIOLATIONS.—Whoever substantially and intentionally violates any requirement of subsection (d) or section 491, 491A, 491B, 492B, or 492C, or any regulation promulgated under such subsection or sections, shall be subject to a civil penalty in an amount that is appropriate for the violation involved, but not to exceed $250,000.''.

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