I

107TH CONGRESS
2D SESSION

H. R. 4697

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

IN THE HOUSE OF REPRESENTATIVES

MAY 9, 2002

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

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A BILL

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

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 ''Human Research Subject Protections Act of 2002''.

SEC. 2. PROTECTION OF HUMAN SUBJECTS IN RESEARCH; UNIFORM NATIONAL APPLICABILITY OF COMMON RULE AND PROVISIONS PROTECTING VULNERABLE POPULATIONS.

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 section:

''PROTECTION OF HUMAN SUBJECTS; UNIFORM NATIONAL APPLICABILITY OF COMMON RULE AND PROVISIONS PROTECTING VULNERABLE POPULATIONS

''SEC. 491A. (a) PROTECTION OF HUMAN SUBJECTS.—

''(1) IN GENERAL.—All human subject research shall be conducted in accordance with the common rule, and as applicable to the human subjects involved in such research, with the vulnerable-populations rules.

''(2) APPLICABILITY.—Paragraph (1) applies to human subject research that—

''(A) is conducted, supported, or otherwise subject to regulation under a provision of Federal law (other than this section), without regard to whether the Federal agency that administers such law has taken administrative action to make the common rule applicable to the agency; or

''(B) is not described in subparagraph (A) and has activities that are in or that affect interstate commerce.

''(b) COMMON RULE; OTHER DEFINITIONS.—

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

''(A) Except as provided in subparagraph (B):

''(i) The term 'common rule' means the provisions of subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulations), subject to subparagraph (C).

''(ii) The term 'vulnerable-population rules' means the provisions of subparts B through D of such part 46 (or any successor regulations), subject to subparagraph (C).

''(B) In the case of human subject research that is subject to the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act:

''(i) The term 'common rule' means the provisions of parts 50 and 56 of title

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

''(ii) The term 'vulnerable-population rules' has the meaning applicable under subpart D of part 50 of such title 21 (or any successor regulations).

''(C) In the case of human subject research to which both of subparagraphs (A) and (B) apply, the terms 'common rule' and 'vulnerable-population rules' have the meaning given such terms in subparagraph (B).

''(2) HARMONIZATION.—

''(A) REVIEW OF REGULATIONS.—Not later than 18 months after the date of the enactment of the Human Research Subject Protections Act of 2002, the Secretary shall complete a review of the provisions of subpart A of part 46 of title 45, Code of Federal Regulations (referred to in this paragraph as 'title 45 regulations'), and the provisions of parts 50 and 56 of title 21, Code of Federal Regulations (referred to in this paragraph as 'title 21 regulations'), in order to determine to what extent the differences in approach between the title 45 regulations and the title 21 regulations can be

harmonized toward the goal of having only such differences as are appropriate to reflect the legal or factual variations in human subject research described in paragraph (1)(B) relative to other human subject research. The areas of difference reviewed shall include (but are not limited to) differences regarding the existence of a significant financial interest; provisions for research relating to emergency interventions; the definition of 'institution'; and requirements for attestations by clinical investigators regarding the protection of human subjects.

''(B) RULEMAKING.—

''(i) PURSUANT TO HARMONIZATION REVIEW.—Not later than three years after completing the review under subparagraph (A), the Secretary shall publish in the Federal Register a proposed rule to modify the title 45 regulations, or the title 21 regulations, or both, in accordance with the findings of the review, unless the review finds that removing any of the differences in approach between the title 45 regulations and the title 21 regulations is not practicable.

"(ii) SUBSEQUENT RULEMAKING.—After the expiration of the three-year period referred to in clause (i), or the publication of the proposed rule under clause (i), whichever occurs first, any rule promulgated by the Secretary that modifies the title 45 regulations or the title 21 regulations (including a modification that adds provisions), and results in there being a difference between the title 45 regulations and the title 21 regulations, shall be accompanied in the Federal Register by a statement of the reasons underlying the determination of the Secretary that, with respect to the goal described in subparagraph (A), the difference is appropriate to reflect the legal or factual variations in human subject research described in paragraph (1)(B) relative to other human subject research.

"(3) HUMAN SUBJECT RESEARCH.—For purposes of this section:

"(A) Except as provided in subparagraphs (B) and (C):

"(i) The term 'human subject research' means clinical research that is conducted with the direct involvement of one or more human subjects.

"(ii) For purposes of the definition established in clause (i), the term 'research' has the meaning that applies for purposes of part 46 of title 45, Code of Federal Regulations (or any successor regulations).

"(B) In the case of an investigation that is subject to the provisions of part 50 of title 21, Code of Federal Regulations (or successor regulations), the term 'human subject research' means clinical research that is a clinical investigation within the meaning of such part 50, except as provided in subparagraph (C).

"(C) The term 'human subject research' does not include the collection, analysis, or abstraction of data contained in records that were made for purposes other than research or investigations conducted with human subjects, including but not limited to business, health, financial, research, marketing, survey, education, or government records.

''(D) The term 'clinical research' has the meaning given such term in section 409(b).

''(E) The term 'human subject' means a living human being.

''(4) OTHER DEFINITIONS.—For purposes of this section:

''(A) The term 'classified', with respect to human subject research, refers to research that, within the meaning of section 552(b)(1)(A) of title 5, United States Code, is—

''(i) specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy; and

''(ii) is in fact properly classified pursuant to such Executive order.

''(B) The term 'data monitoring committee', with respect to human subject research that is a clinical trial, means a group of individuals with appropriate expertise that, on an ongoing basis during the conduct of such trial—

''(i) reviews data that is generated during the trial;

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

"(iii) advises such sponsor on the continued validity and scientific merit of the trial.

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

"(D) The term 'institution served by an Institutional Review Board' means the public or private entity (university, health care provider, health plan, research organization, government agency, or other entity) that establishes and is responsible for the operation of the Institutional Review Board.

"(E) The term 'Institutional Review Board' has the meaning that applies under the common rule.

"(F) The term 'lead Institutional Review Board' means an Institutional Review Board that otherwise meets the requirements of the common rule and enters into a written agreement with an institution, another Institutional Review Board, a sponsor, or a principal investi-

gator to approve and oversee human subject research that is conducted at multiple locations. For purposes of this section, references to an Instutional Review Board include an Institutional Review Board that serves a single institution as well as a lead Institutional Review Board.

''(G) The term 'principal investigator', with respect to human subject research, means the individual who, at the research location involved, has the principal responsibility for the conduct of the research.

''(H)(i) Except as provided in clause (ii), the term 'sponsor', with respect to human subject research, means the entity that has the principal financial responsibility for the conduct of the research.

''(ii) In the case of an investigation that is subject to the provisions of part 50 of title 21, Code of Federal Regulations (or successor regulations), the term 'sponsor', with respect to human subject research, has the meaning that applies for purposes of such part 50.

''(c) SCOPE OF AUTHORITY OF SECRETARY.—

''(1) IN GENERAL.—The common rule (including provisions regarding exemptions) and the vulnerable-populations rules, as in effect on the day before the date of the enactment of the Human Research Subject Protections Act of 2002, continue to be in effect on and after such date, subject to paragraph (2).

''(2) MODIFICATIONS.—

''(A) COMPLIANCE WITH LAW.—Promptly after the date of the enactment of the Act referred to in paragraph (1), the Secretary shall promulgate regulations to make such modifications to the provisions of the common rule as may be necessary to ensure that such provisions implement, and do not conflict with, this section.

''(B) OTHER MODIFICATIONS.—This section may not be construed as affecting the authority of the Secretary to modify the provisions of the common rule or the vulnerable-populations rules, except to the extent that any such modification is in conflict with this section. Any such modification shall be made by regulation.

''(C) AGENCY-SPECIFIC ADDITIONAL PROTECTIONS.—With respect to human subject re-

search that is conducted, supported, or otherwise subject to regulation under a provision of Federal law (other than this section), the Secretary may under subparagraph (A) permit the Federal agency involved to establish additional protections for the protection of human subjects if the Secretary determines that such additional protections are not in conflict with protections established under this section.

''(d) RIGHT OF INFORMED CONSENT.—

''(1) IN GENERAL.—For purposes of subsection (a), a principal investigator, may not, except as provided in the common rule, involve a living individual as a subject in human subject research unless the investigator or other knowledgeable person has obtained the informed consent of the individual to be a subject.

''(2) LEGALLY AUTHORIZED REPRESENTATIVE.—References in this section to obtaining consent from an individual shall be considered to be references to obtaining consent from the legally authorized representative of the individual in any case in which the individual lacks legal competence to provide consent.

''(3) CONSENT FORM.—The consent of an individual to be a human subject in human subject research shall be documented by the principal investigator for the research or another knowledgeable person, and such documentation shall include an acknowledgement by such individual that the individual has with respect to the research been provided a written explanation of the following:

''(A) The purpose of the research.

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

''(C) As applicable to the research, the difference between research and therapeutic treatment.

''(D) The right to cease participation as a subject at any time.

''(E) The identity of the sponsors of the research.

''(F) Any conflict of interest that the investigators have in the research.

''(G) As applicable to the research, the medical tests and procedures that may be necessary as part of the research, and the extent to which the costs of such tests and procedures

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

''(H) Such additional information as the Secretary may require.

''(4) CERTAIN REQUIREMENTS REGARDING DISCLOSURE AND UNDERSTANDING.—The Secretary shall establish criteria regarding consent under paragraph (1) that provide for the following:

''(A) During the process of obtaining consent, a prospective human subject is, through the written explanation provided under paragraph (2) and through written or oral answers to questions from the prospective subject, provided full and complete information relevant to the research involved.

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

''(C) Only an individual who is knowledgeable about the research, and can reasonably be expected to be able to answer questions from

the subject regarding the research, is authorized to provide such information to the subject.

''(D) The written statement under paragraph (2) provides the information required in such paragraph in a clear and conspicuous manner.

''(E) A copy of the documentation of the consent of the subject is provided to the subject, together with information on how to contact the Office of Human Research Protections to submit questions about subjects' rights or to report concerns regarding the research.

''(5) WRITTEN ATTESTATION BY INVESTIGATOR.—A principal investigator who involves a human subject in research shall, in accordance with the criteria of the Secretary, file with the Institutional Review Board for the research a written attestation that the investigator is familiar with requirements for the protection of human subjects, including the requirement of informed consent, and agrees to comply with such requirements.

''(e) INSTITUTIONAL REVIEW BOARDS.—

''(1) REQUIREMENTS FOR BOARDS.—Human subject research may not be conducted unless an Institutional Review Board has, for purposes of the

common rule (and the vulnerable-populations rules, as applicable), approved the proposal for such research. With respect to the research involved, the approval by the Board of the proposal for the research is not effective unless, in addition to conditions established by the Secretary, the following conditions are met:

''(A) Of the membership of such Board:

''(i) Not fewer than two members or 25 percent of all members, whichever is greater, are individuals whose primary expertise is in scientific areas.

''(ii) Not fewer than two members or 20 percent of all members (whichever is greater) are individuals whose primary expertise is in nonscientific areas.

''(iii) Not fewer than two members or 20 percent of all members (whichever is greater) are individuals who are not affiliated with the institution served by the Board (other than by serving on the Board), who are not immediate family members of any individual who is affiliated with the institution, and who do not have

a conflict of interest (including nonproprietary interest).

The appointment of a member of the Board to meet the requirement of clause (iii) also qualifies toward meeting the requirement of clause (ii) if the primary expertise of such member is in a nonscientific area.

''(B) When reviewing a proposal for research that is designed to include as a subject an individual who is a member of a vulnerable population, the Board includes at least one member who is an expert in the issues involving such population; allows such member to fully participate in the Board review process; and provides such member with the same voting rights as other members of the Board. The appointment of a member of the Board to meet the requirement of this subparagraph may also qualify toward meeting the requirement of clause (ii) of subparagraph (A), or clause (iii) of such subparagraph, if such member satisfies the criteria described in the clause involved.

''(C) When reviewing a proposal for research that is designed to include as subjects a significant number of minority individuals (as

defined in section 485E(c)), the Board includes minority members; allows such members to fully participate in the Board review process; and provides such members with the same voting rights as other members of the Board. The appointment of a member of the Board to meet the requirement of this subparagraph may also qualify toward meeting the requirement of clause (ii) of subparagraph (A), or clause (iii) of such subparagraph, if such member satisfies the criteria described in the clause involved.

''(D)(i) In reviewing a proposal for research, the Board does not consider a quorum to have been established for a meeting unless the members present at the meeting include one or more members from each of the three categories described in subparagraph (A).

''(ii) In any case in which the Board will under subparagraph (C) review a proposal for research that is designed to include as subjects a significant number of minority individuals, the Board does not consider a quorum to have been established for a meeting unless the members present at the meeting include the members required under such subparagraph.

''(E) The institution served by the Board ensures that the Board has an orientation program for new members and a continuing education program for existing members of the Board, and with respect to ethical matters that relate to research, a continuing education program for all members of the Board.

''(F) The institution served by the Board has submitted to the Secretary a registration informing the Secretary of the existence of the Board, and the registration was in such form, was made in such manner, and contained such information as the Secretary requested regarding functions of the Board under this section.

''(G) In the case of a proposal for a high risk trial, the Board reviews the data safety and monitoring plan of the data monitoring committee (operated pursuant to subsection (f)) as a part of the review by the Board of the proposal.

''(H) With respect to the research involved, each member of the Board has disclosed to the institution served by the Board, and such institution has disclosed to the Board, any actual conflicts of interest, or interests that create the

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

"(i) involvement as investigators in the research;

"(ii) ownership interests in the research; and

"(iii) direct financial relationships or arrangements with private sponsors of the research, excluding ownership of any independently-managed investment plan (such as mutual funds) that may own a financial interest in such a sponsor.

"(I) A member of the Board does not participate in the review by the Board of a proposal for research if the member has a conflict of interest (including a nonproprietary interest) in the research. The provision by such member of information to other members of the Board does not constitute Board participation for purposes of this subparagraph.

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

research projects reviewed, the number of human subjects involved in approved research, and any additional information determined appropriate by the Secretary.

''(K) The institution served by the Board submits to the Secretary such reports regarding the Board as the Secretary determines to be appropriate.

''(2) NOTIFICATION OF INSTITUTIONAL REVIEW BOARD BY INVESTIGATORS.—In submitting to an Institutional Review Board a proposal for human subject research, the investigators for the research shall notify the Board, and the institution served by the Board—

''(A) of any actual conflicts of interest, or interests that create the appearance of a conflict of interest;

''(B) whether the investigators have been disqualified or restricted by any Federal entity in their ability to conduct human subject research, including being ineligible to conduct human subject research with investigational new drugs, being ineligible for approval of new drug applications, or agreeing to some other form of restriction regarding research; and

''(C) whether the proposal has been submitted by the principal investigator to any other Institutional Review Board.

''(3) INSTITUTION REVIEW OF CONFLICTS OF INTEREST.—The institution served by an Institutional Review Board shall review such conflicts of interest or interests that create the appearance of a conflict of interest as are submitted under paragraph (2) and shall seek to reduce or eliminate and shall oversee such conflicts of interest, with respect to the research.

''(4) PROJECTS INVOLVING MULTIPLE LOCATIONS.—For purposes of meeting the common rule requirements for review and supervision of research by an Institutional Review Board, such activities may be performed by an Institutional Review Board or a lead Institutional Review Board, at the option of the institution where the research is conducted.

''(5) VOLUNTARY ACCREDITATION.—The Secretary may in accordance with this paragraph facilitate the accreditation of Institutional Review Boards and institutions by a private accrediting entity or entities. For purposes of the preceding sentence:

''(A) The Secretary may recognize an accrediting entity if the accrediting entity submits

to the Secretary the accrediting standards of the entity, the Secretary determines that the standards further the purposes of this section, and the accrediting entity annually submits to the Secretary a report describing any changes in the accrediting standards or procedures of the entity.

''(B) The Secretary shall biannually evaluate the performance of the accrediting entity.

''(C) The Secretary may withdraw recognition of the accrediting entity if the Secretary determines that the requirements of subparagraph (A) are not met.

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

''(6) COST RECOVERY.—Institutions may recover costs associated with compliance for human subject protections under this Act from government sponsors of research as direct costs.

''(f) IMPROVED MONITORING OF HIGH RISK CLINICAL TRIALS.—With respect to human subjects in high risk clinical trials:

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

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

"(A) a provision that the Secretary may require the sponsor of the trial to utilize a data monitoring committee in affiliation with the trial;

"(B) minimum requirements for the reporting by the principal investigator of information on such plan to the Institutional Review Board for the trial and to the institution served by the Board; and

"(C) the requirement that such committee provide reports on the findings of the committee regarding the trial to such investigator, Board, and institution.

"(2) The Secretary shall require that adverse events in such a trial be reported by the principal investigator for the trial in a timely manner appropriate to whether the event is unexpected and its severity to the Institutional Review Board for the trial, and to the sponsor of the trial. Such events shall in addition be reported by the principal investigator to the Director of the Office of Human Research Protections, or the Commissioner of Food and Drugs, whichever administers the common rule as applied to

the trial. Such regulations shall ensure comprehensive and coordinated reporting to all relevant parties.

''(g) INSTITUTIONAL PROGRAMS OF EDUCATION.—For fiscal year 2003 and subsequent fiscal years, the Secretary may not make an award of a grant, cooperative agreement, or contract under this Act to a public entity or a private academic institution, or make an award of a grant, cooperative agreement, or contract under this Act for the conduct of research at or through or in affiliation with a public entity or a private academic institution, unless the public entity or private academic institution (as the case may be) maintains or contracts for a comprehensive and ongoing program to educate investigators and Board members on the protection of human subjects in research.

''(h) CERTAIN CLASSIFIED HUMAN SUBJECT RESEARCH.—Notwithstanding any other provision of law, Federal funds may not be expended for the conduct of classified human subject research if—

''(1) the Institutional Review Board reviewing the proposal for the research pursuant to this section has under the common rule waived the requirement to obtain the informed consent of the human subjects in the research; or

''(2) the research is exempt from the requirement under the common rule that the proposal for the research be reviewed by such a Board.

''(i) DISCLOSURE OF VIOLATIONS.—

''(1) DISCLOSURES.— Upon the request of an entity that conducts or supports research, or upon the request of an Institutional Review Board, the Secretary shall determine whether another entity (including an individual, as applicable under the request) has violated any requirement under this section, and shall disclose to such entity or Board the findings of the Secretary.

''(2) NOTICE TO SUBJECT OF DISCLOSURE.—If pursuant to a request under paragraph (1) the Secretary discloses that an entity has violated a requirement under this section, the Secretary shall in writing notify the entity of the disclosure, including the identity of the entity or Institutional Review Board to which the disclosure was made.

''(j) APPLICABILITY OF REQUIREMENTS.—The requirements of this section apply on and after the date of the enactment of the Human Research Subject Protections Act of 2002.''.

SEC. 3. OFFICE OF HUMAN RESEARCH PROTECTIONS.

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

''OFFICE OF HUMAN RESEARCH PROTECTIONS

''SEC. 491B. (a) IN GENERAL.—There is established within the Office of the Secretary an office to be known as the Office of Human Research Protections (in this section referred to as the 'Office'). The Office shall be headed by a director, who shall be appointed by the Secretary. The Secretary shall carry out this section acting through the Director of the Office.

''(b) CERTAIN DUTIES.— The Director of the Office—

''(1) shall provide for the protection of human subjects in research by carrying out activities in accordance with subsection (c) regarding compliance with the common rule, as defined in and modified pursuant to section 491A;

''(2) shall establish criteria regarding assurances of compliance with the requirements of the common rule;

''(3) shall coordinate activities within the Department of Health and Human Services, and coordinate the activities of the Department with other

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

''(4) may, in collaboration with the Director of NIH and the Commissioner of Food and Drugs, carry out educational and quality improvement programs for human subject protections for principal investigators, members of Institutional Review Boards, and other appropriate persons, including the generation of resource materials relating to the responsibilities of the research community for the protection of human subjects in research;

''(5) shall, upon the request of an entity that conducts or supports human subject research, consult with the entity regarding improvements in human subject protections in such research;

''(6) may make grants to entities that conduct or support human subject research for the purpose of assisting the entities in carrying out programs to recruit and train minority individuals (as defined in section 485E(c)) to serve as members of Institutional Review Boards;

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

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

''(e) MODEL EDUCATION PROGRAM.—The Director of the Office may make grants for the development of a model education program to be used by institutions served by Institutional Review Boards to satisfy the requirements under section 491A(e)(1)(E) and to develop best practices in institutional management of clinical trials.

''(d) COMPLIANCE AND ENFORCEMENT.—

''(1) AUDITS OF INVESTIGATORS AND INSTITUTIONS.—The Director of the Office may conduct audits of entities that conduct or support human subject research in order to determine whether such entities are complying with the common rule.

''(2) CORRECTIVE ACTION PLAN.—If the Director of the Office determines that an entity referred to in paragraph (1) is not in compliance with the common rule, the Director of the Office, after providing to an appropriate representative of the entity an oral or written summary of the reasons underlying such determination, may require the entity to develop and to implement a plan for corrective action to bring the entity into compliance.

''(3) RESTRICTIONS.—If the Director of the Office determines that an entity referred to in paragraph (1) is not in compliance with the common rule, the Director may impose restrictions on the extent to which the entity may conduct or support human subject research. The restrictions may include any of the following:

''(A) Suspending research protocols.

''(B) Prohibiting the inclusion of additional human subjects in particular research projects.

''(C) Suspending or terminating particular research projects, unless doing so would endanger the human subjects participating in such projects.

''(D) Suspending the provision of Federal funds for particular research projects conducted or supported by or through the entity, or for particular research protocols of the entity.

''(E) Suspending the provision of Federal funds for all research projects conducted or supported by or through the entity, in any case in which the Secretary determines that the noncompliance creates a significant threat to the rights and welfare of human subjects in such projects.

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

''(i) suspending or debarring the individuals from receiving Federal funds for conducting human subject research; or

''(ii) suspending or debarring the individuals from serving as principal investigators in human subject research.

''(4) INSTITUTIONAL REVIEW BOARDS.—

''(A) AUDITS.—In carrying out paragraph (1), the Director of the Office may conduct audits of Institutional Review Boards in order to determine whether such Boards are complying with the common rule (including conditions described in section 491A(e)).

''(B) CORRECTIVE ACTION PLAN.—If the Director of the Office determines that an Institutional Review Board is not in compliance with the common rule, the Director of the Office, after providing to an appropriate representative of such Board, or of the institution served by the Board, an oral or written summary of the reasons underlying such determination, may require the Board to develop and to implement a

plan for corrective action to bring the Board into compliance.

''(C) RESTRICTIONS.—If the Director determines that an Institutional Review Board is not in compliance with the common rule, the Director may—

''(i) in the case of the research projects with respect to which the Board was or is not in compliance, provide that the approvals of the Board for such projects are not effective for purposes of section 491A(e)(1), unless such projects were approved by another Institutional Review Board; or

''(ii) may provide that all approvals of research by the Board are not effective for purposes of such section, in any case in which the Director determines that the noncompliance creates a significant threat to the rights and welfare of human subjects in projects approved by the Board.

''(D) PROJECTS INVOLVING MULTIPLE LOCATIONS.—In the case of a project of human subject research for which there is an agreement under section 491A(b)(4)(F) (relating to

multiple Institutional Review Boards), the Director of the Office shall, in carrying out authorities under this subsection with respect to an Institutional Review Board, ensure that no action is taken that adversely affects the operation of a project of human subject research at any project location for which such Institutional Review Board had no responsibilities.

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

''(6) COORDINATION WITH FOOD AND DRUG ADMINISTRATION.—In the case of human subject research that is subject to the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act, no authority under this subsection may be carried out with respect to an entity that conducts or supports such research, or with respect to an Institutional Re-

view Board, unless the Commissioner of Food and Drugs concurs in the exercise of the authority involved.

''(e) FUNDING.—

''(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose 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 fiscal year 2004 and each subsequent fiscal year.

''(2) MODEL EDUCATION PROGRAM.—For the purpose of carrying out subsection (c), there are authorized to be appropriated such sums as may be necessary for fiscal year 2003 and each subsequent fiscal year.

''(3) RULE OF CONSTRUCTION.—Nothing in this section or section 491A may be construed as a change in the budget authority or authorization of appropriations for the Food and Drug Administration.''.

SEC. 4. AMENDMENTS REGARDING PROCESS FOR RESPONDING TO REPORTS OF VIOLATIONS.

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

(1) in the first sentence, by inserting ''or the Director of the Office of Human Research Protections'' after ''the Director of NIH''; and

(2) in the second sentence, by inserting after ''this Act'' the following: '', the sharing of information between the Director of NIH and the Director of such Office, and''.

SEC. 5. NATIONAL RESEARCH PROTECTIONS ADVISORY COMMITTEE.

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

SEC. 6. ENHANCED HUMAN SUBJECT PROTECTIONS FOR PEOPLE WITH DIMINISHED DECISIONMAKING CAPACITY.

Not later than three years after the date of the enactment of this Act, the Secretary of Health and Human Services shall, for purposes of section 491A of the Public Health Service Act, promulgate regulations to enhance the protection of people with diminished decisionmaking capacity with respect to their participation as subjects in human subject research.

SEC. 7. RULE OF CONSTRUCTION REGARDING INDIVIDUAL AGENCY OFFICES.

The amendments made by this Act may not be construed as terminating any office or other administrative unit in a Federal agency that, on the day before the date of the enactment of this Act, had duties relating to the protection of human subjects in research conducted, supported, or otherwise subject to regulation under Federal law.

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