I

108TH CONGRESS
1ST SESSION

H. R. 3594

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

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 21, 2003

Ms. DEGETTE 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 ''Protection for Participants in Research Act of 2003''.

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 part 56 of such title 21 (or any successor regulations), and includes the provisions of subpart D of part 50 of such title 21 (or any successor regulations).

''(C) In the case of human subject research to which both 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 Protection for Participants in Research Act of 2003, 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 ap-

proach 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 subparagraph (B), the term 'human subject research' means research, as defined in subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulations), that involves a human subject, as defined in such subpart A (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' has the meaning given such term in such part 50, and the term 'human subject research' means a clinical investigation as defined in such part 50.

"(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 safety and monitoring committee', with respect to a human subject research project, means a group of individuals with appropriate expertise that, on an ongoing basis during the conduct of such research project—

"(i) reviews data that is generated during the project;

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

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

"(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 investigator to approve and oversee human subject research that is conducted at multiple locations. For purposes of this section, references to an Institutional 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 sub-

ject 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 Protection for Participants in Research Act of 2003, 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) CONSIDERATION OF CERTAIN MATTERS.—

''(i) IN GENERAL.—Not later than 18 months after the date of the enactment of the Protection for Participants in Research Act of 2003, the Secretary shall, with respect to the Common Rule—

''(I) consider the matters specified in clause (ii) and make a determination of whether any of the provisions of such Rule should be modified accordingly; and

''(II) publish the determination in the Federal Register.

''(ii) LIST OF MATTERS FOR CONSIDERATION.—The matters referred to in

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

''(I) Whether the list of exemptions from applicability of the Common Rule, as in effect on the day before the date of enactment referred to in clause (i), should be modified or new categories of exemptions established.

''(II) Whether there are circumstances in which research that studies human tissue or other types of clinical specimens should not be considered human subject research.

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

''(IV) Whether the list of expedited procedures under the Common Rule, as in effect on the day before the date of enactment referred to in clause (i), should be modified or new categories of expedited procedures established.

''(V) Whether modified procedures should apply to human subject research

that poses minimal risk to the subjects, including whether there are any types of such research for which some aspect of the requirement of informed consent or documentation of informed consent should apply differently.

''(VI) Whether Institutional Review Boards include sufficient numbers of minority individuals (as defined in section 485E(c)) as Board members when reviewing proposals designed to have a population of human subjects a majority of whom are minority individuals.

''(VII) Such additional matters as the Secretary determines to be appropriate.

''(D) AGENCY-SPECIFIC ADDITIONAL PROTECTIONS.—With respect to human subject research 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 an 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) CERTAIN REQUIREMENTS REGARDING DISCLOSURE AND UNDERSTANDING.—The Secretary shall establish criteria regarding consent under paragraph (1) that—

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

"(B) require such information to be provided in language understandable to such subject;

"(C) require that only individuals knowledgeable about the research provide such information to the subject and answer questions from the subject; and

"(D) require that information be provided to the subject on how to contact the Office for Human Research Protections to submit questions about the rights of subjects or to report concerns regarding the research.

"(4) 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 significant conflict of interest, as defined by applicable Federal regulations.

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) 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).

''(C) 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.

''(D) 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.

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

''(F) With respect to the research involved, each member of the Board has disclosed any significant financial interests, as defined by applicable Federal regulations, to the institution served by the Board, and such institution has disclosed any such disclosures to the Board.

''(G) A member of the Board does not participate in the review by the Board of a proposal for research if the member has a significant conflict of interest, as defined by applicable Federal regulations, 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.

''(H) 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 reviewed biomedical research proposals, the number of reviewed behaviorial or social sciences research proposals, and any additional information determined appropriate by the Secretary.

''(I) 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 institution served by the Board—

''(A) of any significant financial conflicts of interest, as defined by applicable Federal regulations;

''(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 significant financial conflicts of interest as are submitted under paragraph (2) to determine whether such interests create or may reasonably appear to create conflicts of interest, and then shall seek to manage, reduce, or eliminate such conflicts of interest.

''(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 institutions and Institutional Review Boards by recognizing a private ac-

crediting entity or entities. For purposes of the preceding sentence:

"(A) The Secretary may recognize an accrediting entity if—

"(i) such entity submits to the Secretary the standards and procedures that the entity requires institutions and Institutional Review Boards to meet in order to be accredited by the entity;

"(ii) the Secretary determines that such standards and procedures include standards and procedures ensuring that the policies and procedures of institutions and Institutional Review Boards accredited by the entity are in compliance with Federal regulations governing human subject research; and

"(iii) the entity annually submits to the Secretary a report describing any changes in the standards and procedures described in clause (ii).

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

in research, or any component thereof, be accredited.

''(C) Nothing in this section may be construed as authorizing the Secretary—

''(i) to establish or approve accreditation standards or procedures for institutions, Institutional Review Boards, or programs for the protection of human subjects in research, or any component thereof; or

''(ii) to recognize any standards or procedures for institutions or Institutional Review Boards other than the standards and procedures described in subparagraph (A)(ii).

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

''(f) IMPROVED MONITORING OF HIGH-RISK RESEARCH.—With respect to high-risk human subject research projects:

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

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

"(B) minimum requirements for the reporting by the principal investigator of information on such plan to the Institutional Review Board for the research project 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 research project to such investigator, Board, and institution.

"(2) The Secretary shall require that an adverse event in the research project be reported by the principal investigator to the Institutional Review Board for the research project, and to the sponsor of the research project, in a timely manner appropriate to the severity of the event and whether the event is unexpected. Such events shall in addition be reported by the principal investigator as directed by the Secretary. Such regulations shall ensure comprehensive and coordinated reporting to all relevant parties.

''(g) INSTITUTIONAL PROGRAMS OF EDUCATION.—For fiscal year 2004 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 Institutional Review Board, the Secretary shall determine whether an entity (including an individual, as applicable under the request) has violated any requirement under this section, and shall disclose to such 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 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 Protection for Participants in Research Act of 2003.''.

SEC. 3. OFFICE FOR 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 FOR 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 for 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 (d) 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 direct 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 subjects in human subject research;

''(4) may, in collaboration with the Director of NIH, the Commissioner of Food and Drugs, or the head of any other Federal department or agency, 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—

''(A) consult with the entity regarding improvements in human subject protections in such research; and

''(B) provide advice on compliance with the Common Rule, including with respect to differing interpretations among Institutional Review Boards of a provision of such Rule;

''(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.

''(c) 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)(C) and to develop best practices in institutional management of human subject research.

''(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 para-

graph (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 described in section 491A(b)(4)(F) (relat-

ing 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 2004, and such sums as may be necessary for fiscal year 2005 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 2004 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 for 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. 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. 6. 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, sup-

ported, or otherwise subject to regulation under Federal law.

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