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112TH CONGRESS
1ST SESSION

H. R. 2625

To amend the Public Health Service Act with respect to human subject research to improve protections for human subjects and, where appropriate because of the type research involved, to reduce regulatory burdens.

IN THE HOUSE OF REPRESENTATIVES

JULY 22, 2011

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 human subject research to improve protections for human subjects and, where appropriate because of the type research involved, to reduce regulatory burdens.

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 Participants Protection Modernization Act of 2011''.

SEC. 2. PROTECTION OF HUMAN SUBJECTS IN RESEARCH; APPLICABILITY OF RULES.

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:

"SEC. 491A. PROTECTION OF HUMAN SUBJECTS IN RESEARCH; APPLICABILITY OF RULES.

''(a) PROTECTION OF HUMAN SUBJECTS.—

''(1) IN GENERAL.—Except as provided in paragraph (2), all human subject research described in paragraph (3)(A) shall be conducted in accordance with the HHS Human Subject Regulations, and as applicable to the human subjects involved in such research, with the vulnerable-populations rules.

''(2) FDA RESEARCH.—

''(A) APPLICABLE RULES.—All human subject research that is subject to the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act shall be conducted—

''(i) in accordance with the provisions of parts 50, 56, 312, and 812 of title 21, Code of Federal Regulations (or any successor regulations); and

''(ii) as applicable to the human subjects involved in such research, in accordance with provisions applicable to vulner-

able populations under part 56 of such title 21 (or any successor regulations) and subpart D of part 50 of such title 21 (or any successor regulations).

''(B) REFERENCES.—In the case of human subject research described in subparagraph (A)—

''(i) each reference in this section or section 491B to the HHS Human Subject Regulations shall be treated as a reference to the provisions described in subparagraph (A)(i); and

''(ii) each reference in this section to the vulnerable population rules shall be treated as a reference to the provisions described in subparagraph (A)(ii).

''(3) APPLICABILITY.—

''(A) IN GENERAL.—This section applies to human subject research that is—

''(i) conducted or supported by the Department of Health and Human Services; or

''(ii) otherwise subject to regulation by the Department under a provision of Federal law (other than this section).

''(B) OTHER FEDERAL DEPARTMENTS AND AGENCIES.—The Secretary shall make available assistance to any Federal department or agency seeking—

''(i) to improve the regulation or oversight of human subject research; or

''(ii) to apply the HHS Human Subject Regulations or the vulnerable-population rules to human subject research that is conducted, supported, or regulated by such department or agency.

''(b) HHS HUMAN SUBJECT REGULATIONS; OTHER DEFINITIONS.—

''(1) HHS HUMAN SUBJECT REGULATIONS; VULNERABLE-POPULATION RULES.—For purposes of this section:

''(A) Except as provided in subsection (a)(2)(B) (relating to FDA research), the term 'HHS Human Subject Regulations' means the provisions of subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulations).

''(B) Except as provided in subsection (a)(2)(B) (relating to FDA research), the term 'vulnerable-population rules' means the provi-

sions of subparts B through D of such part 46 (or any successor regulations).

''(2) 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.

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

''(A) The terms 'institution served by an institutional review board' and 'institution served by the board' mean the public or private entity (university, health care provider, health plan, research organization, government agency,

independent institutional review board, or other entity) that establishes and is responsible for the operation of the institutional review board.

"(B) The term 'institutional review board' has the meaning that applies to the term 'institutional review board' under the HHS Human Subject Regulations.

"(C) The term 'lead institutional review board' means an institutional review board that otherwise meets the requirements of the HHS Human Subject Regulations 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.

"(D) 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.

''(E)(i) Except as provided in clause (ii), the term 'sponsor', with respect to human subject research, means the entity that provides the majority or plurality of the financial support 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 HHS Human Subject Regulations (including provisions regarding exemptions) and the vulnerable-populations rules, as in effect on the day before the date of the enactment of the Research Participants Protection Modernization Act of 2011, 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 HHS Human

Subject Regulations 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 HHS Human Subject Regulations 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.—The Secretary shall, with respect to the HHS Human Subject Regulations, consider the matters specified in clause (iii) and make a determination of whether any of the provisions of such Rule or any guidance associated with such Rule should be modified accordingly.

"(ii) TIMING.—The Secretary shall publish the determination required by clause (i) in the Federal Register—

''(I) except as provided in subclause (II), not later than 3 years after the date of the enactment of the Research Participants Protection Modernization Act of 2011; and

''(II) in the case of a determination on the matters specified in clause (iii)(IX), not later than 18 months after the submission of the report required by section 5 of the Research Participants Protection Modernization Act of 2011.

''(iii) LIST OF MATTERS FOR CONSIDERATION.—The matters referred to in clause (i) with respect to the HHS Human Subject Regulations are the following:

''(I) How requirements regarding the definition and management of potential financial conflict of interest, including both investigator and institutional conflicts of interest, should be strengthened and enforced to protect human subjects more effectively.

''(II) Whether the list of exemptions from applicability of the HHS

Human Subject Regulations, as in effect on the day before the date of enactment referred to in clause (ii)(I), should be expanded to include new categories.

''(III) Whether and under what circumstances research that studies human tissue or other types of clinical specimens should not be considered a clinical investigation.

''(IV) Whether the list of categories of research that are eligible for expedited review under the HHS Human Subject Regulations, as in effect on the day before the date of enactment referred to in clause (ii)(I), should be expanded to include new categories of research eligible for expedited review.

''(V) Whether institutional review boards include sufficient numbers of minority individuals as board members when reviewing proposals designed to include human subjects who are minority individuals.

''(VI) Whether the requirements for the number of members of an institutional review board who are individuals whose primary expertise is in nonscientific areas, and the number of members of an institutional review board who are individuals who are not affiliated with the institution served by the board, should be increased.

''(VII) Whether institutional review boards include sufficient numbers of individuals with appropriate scientific expertise.

''(VIII) How to enhance the protection of people with diminished decisionmaking capacity with respect to their participation as subjects in human subject research.

''(IX) How the requirements for institutional review board review in multisite research should be modified to reduce regulatory burden while protecting human subjects, including use of a lead institutional review board.

''(X) How the requirements for managing and reporting adverse events and unanticipated problems should be modified—

''(aa) to increase consistency between such requirements of the Office for Human Research Protections of the Department of Health and Human Services and the corresponding requirements of the Food and Drug Administration; and

''(bb) to reduce regulatory burden appropriately while protecting human subjects.

''(XI) How the requirements for approval and oversight of human subjects research that poses no more than minimal risk to participants (including requirements of informed consent, documentation of informed consent, and continuing review) should be modified to reduce regulatory burden (including burden on institutions, institutional review boards, and inves-

tigators) while protecting research participants, including clarification of the circumstances in which informed consent does not need to be writing.

''(XII) Whether research that would be defined as a 'clinical investigation' under part 50 of title 21, Code of Federal Regulations, should comply with the guideline published by the Food and Drug Administration and endorsed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, entitled 'Good Clinical Practice: Consolidated Guideline', and how investigators can be educated effectively regarding compliance with this guideline.

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

''(d) INSTITUTIONAL REVIEW BOARDS.—

''(1) NOTIFICATION OF INSTITUTIONAL REVIEW BOARD AND SPONSORS BY INVESTIGATORS.—

''(A) REQUIREMENT.—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—

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

''(ii) whether the investigators have been disqualified or restricted by any Federal, State, or local 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

''(iii) whether the proposal has been submitted to any other institutional review board and, as applicable, of any findings made by such board.

''(B) TIMING.—A notification required by subparagraph (A) shall be submitted to the institution served by the board—

''(i) at the time of submitting the proposal for human subject research to the board; or

''(ii) in the case of circumstances arising after such submission, immediately.

''(2) INSTITUTIONAL REVIEW OF CONFLICTS OF INTEREST.—The institution served by an institutional review board shall—

''(A) review such significant financial interests as are submitted to the institution under paragraph (1) to determine whether such interests create or may reasonably appear to create conflicts of interest; and

''(B) seek to eliminate or manage such conflicts of interest.

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

''(e) INSTITUTIONAL PROGRAMS OF EDUCATION.—For fiscal year 2012 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 program to educate investigators and board members on the protection of human subjects in research.

''(f) APPLICABILITY OF REQUIREMENTS.—The requirements of this section apply on and after the date of the enactment of the Research Participants Protection Modernization Act of 2011.''.

SEC. 3. OFFICE FOR HUMAN RESEARCH PROTECTIONS.

(a) IN GENERAL.—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:

''SEC. 491B. OFFICE FOR HUMAN RESEARCH PROTECTIONS.

''(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 section 491A;

''(2) shall establish criteria regarding assurances of compliance with the requirements of section 491A;

''(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 section 491A, including with respect to differing interpretations among institutional review boards of a provision of such section;

''(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 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 PROGRAMS.—The Director of the Office may make grants for the development of model education programs that may be used by institutions served by institutional review boards to promote best practices in institutional management of human subject research.

''(d) 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 2012, and such sums as may be necessary for fiscal year 2013 and each subsequent fiscal year.

''(2) MODEL EDUCATION PROGRAMS.—For the purpose of carrying out subsection (c), there are authorized to be appropriated such sums as may be necessary for fiscal year 2012 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.''.

(b) FUNCTIONS, PERSONNEL, ASSETS, AND LIABILITIES.—All functions, personnel, assets, and liabilities of the Office for Human Research Protection of the Department of Health and Human Services, as in existence on the day before the date of the enactment of this Act, shall be transferred to the Office for Human Research Protections established by section 491B of the Public Health Service Act, as added by subsection (a).

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: '', sharing of information between the Director of NIH and the Director of such Office,''.

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