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106TH CONGRESS
2D SESSION

H. R. 3569

To amend the Public Health Service Act to establish an independent office to be known as the Office for Protection of Human Research Subjects, and to assign to such Office responsibility for administering regulations regarding the protection of human subjects in Federal research projects.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 2, 2000

Mr. KUCINICH (for himself, Mr. TOWNS, Mr. LATOURETTE, Mr. WAXMAN, and Mr. SANDERS) introduced the following bill; which was referred to the Committee on Commerce

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A BILL

To amend the Public Health Service Act to establish an independent office to be known as the Office for Protection of Human Research Subjects, and to assign to such Office responsibility for administering regulations regarding the protection of human subjects in Federal research projects.

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 Protection and Promotion Act of 2000''.

SEC. 2. ESTABLISHMENT OF INDEPENDENT OFFICE FOR PROTECTION OF HUMAN RESEARCH SUBJECTS.

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended by adding at the end the following:

''TITLE XXVIII—PROTECTION OF HUMAN RESEARCH SUBJECTS

''SEC. 2801. OFFICE FOR PROTECTION OF HUMAN RESEARCH SUBJECTS.

''(a) IN GENERAL.—There is established as an independent establishment in the executive branch an office to be known as the Office for Protection of Human Research Subjects (in this title referred to as the 'Office'), which shall be headed by a director appointed by the President.

''(b) PROTECTION OF SUBJECTS.—

''(1) IN GENERAL.—The Director of the Office shall by regulation establish criteria for the protection of human subjects in research conducted, supported, or otherwise subject to regulation by the Federal Government (in this title referred to as 'Federal research projects'), including provisions regarding the informed consent of individuals to serve as such subjects.

''(2) REGULATIONS.—

''(A) IN GENERAL.—In the case of covered Federal agencies under subsection (c)—

''(i) regulations promulgated under paragraph (1) by the Director of the Office supersede all regulations for criteria described in such paragraph that were in effect on the day before the date of the enactment of the Human Research Protection and Promotion Act of 2000, subject to subparagraph (B); and

''(ii) on and after such date of enactment, the Director of the Office has exclusive authority to issue regulations for criteria described in paragraph (1).

''(B) CERTAIN REGULATIONS.—Effective on the date of the enactment of the Human Research Protection and Promotion Act of 2000, all provisions of part 46 of title 45, Code of Federal Regulations, are deemed to have been promulgated under paragraph (1) by the Director of the Office. Subject to subsection (c), such provisions continue to be in effect, and such provisions may be modified by the Director of the Office by regulation.

''(c) APPLICABILITY OF REGULATIONS.—

''(1) COVERED FEDERAL AGENCIES.—Except as provided in paragraphs (2) through (4), regulations under subsection (b) apply—

''(A) to each Federal agency that, as of October 1, 1999, was subject to the policy under subpart A of part 46 of title 45, Code of Federal Regulations (including Federal agencies that, pursuant to section 101(a) of such part, were subject to such policy by reason of having taken appropriate administrative action); and

''(B) to each Federal agency that takes appropriate administrative action after October 1, 1999, to provide that regulations under subsection (b) apply to the agency.

''(2) EXEMPTIONS.—The Director of the Office may by regulation exempt any Federal research project from the applicability of regulations under subsection (b). Exemptions under the preceding sentence may be established for a specified project or for categories of projects, including a category providing that all Federal research projects of an agency are exempt.

''(3) OTHER EXEMPTIONS.—The exemptions described in section 46.101(b) of title 45, Code of Federal Regulations, as of the date of the enactment

of the Human Research Protection and Promotion Act of 2000 continue to be in effect unless modified by the Director of the Office.

''(4) CERTAIN REGULATIONS.—In the case of a covered Federal agency that, as of the date of the enactment of the Human Research Protection and Promotion Act of 2000, was not subject to the provisions of subparts B through D of part 46 of title 45, Code of Federal Regulations, the applicability of such provisions to Federal research projects of the agency pursuant to paragraph (1) is subject to the condition that such provisions apply only to Federal research projects of the agency that are approved on or after such date of enactment.

''(d) CONSULTATIONS.—In making any modifications to regulations under subsection (b), the Director of the Office shall consult with the other members of the Interagency Committee under section 2803.

''SEC. 2802. INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM.

''(a) IN GENERAL.—In carrying out section 2801(b), the Director of the Office shall comply with the following:

''(1) The Director shall require that each entity that applies to carry out a Federal research project under a grant, contract, or cooperative agreement

from a covered Federal agency submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Director that the entity has established a board, to be known as an Institutional Review Board, to review such projects at or supported by the entity in order to protect the rights of the human subjects in such projects.

''(2) The Director shall establish a program under which requests for clarification and guidance with respect to ethical issues raised in connection with Federal research projects are responded to promptly and appropriately.

''(3) The Director shall establish a process for the prompt and appropriate response to information provided to any Federal agency regarding violations of the rights of human subjects in Federal research project. The process shall include procedures for receiving reports regarding possible violations and for taking appropriate action with respect to such violations.

''(b) CERTAIN INSTITUTIONAL REVIEW BOARDS.—Any board that, on the day before the date of the enactment of the Human Research Protection and Promotion Act of 2000, was considered to be an Institutional Review

Board under section 491(a) of this Act (as in effect on such day) shall be considered to be an Institutional Review Board that meets the requirements of subsection (a) of this section unless notified otherwise by the Director of the Office.

"SEC. 2803. INTERAGENCY COORDINATING COMMITTEE.

''(a) IN GENERAL.—The Director of the Office shall establish a committee to be known as the Interagency Coordinating Committee on Protection of Human Research Subjects (in this title referred to as the 'Interagency Committee').

''(b) DUTIES.—The Interagency Committee shall develop recommendations on carrying out this title, including recommendations on coordinating the administration of regulations under section 2801(b) at the various Federal agencies with responsibilities regarding Federal research projects.

''(c) COMPOSITION; CHAIR.—The Interagency Committee shall be composed of the Director of the Office and the heads of covered Federal agencies (or the designees of the Director of the Office and the agency heads). The Director of the Office (or the designee of the Director) shall serve as the chair of the Interagency Committee.

''(d) REVIEW OF REGULATIONS; REPORT TO CONGRESS.—

''(1) IN GENERAL.—Not later than one year after the date of the enactment of the Human Research Protection and Promotion Act of 2000, the Interagency Committee—

''(A) shall complete a review of regulations under section 2801(b), including a review of—

''(i) regulations deemed to have been promulgated by the Director of the Office pursuant to section 2801(b)(2)(B); and

''(ii) the exemptions referred to in section 2801(c)(3);

''(B) shall make such recommendations regarding the regulations as the Interagency Committee determines to be appropriate; and

''(C) shall submit to the congressional committees specified in paragraph (2) a report describing the activities carried out under subparagraph (A) and any recommendations regarding such regulations.

''(2) CONGRESSIONAL COMMITTEES.—The congressional committees referred to in paragraph (1)(C) are the Committee on Commerce and the Committee on Government Reform in the House of Representatives, and the Committee on Health, Education, Labor, and Pensions in the Senate.

"SEC. 2804. CERTAIN ADMINISTRATIVE AUTHORITIES.

''In carrying out this title, the Director of the Office—

''(1) may 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) may 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) may enter into contracts, subject to the availability of amounts made available in appropriations Act, 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) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement;

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

''(6) may accept voluntary and uncompensated services.

''SEC. 2805. DEFINITIONS.

For purposes of this title:

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

''(2) The term 'by regulation' refers to rulemaking in accordance with the procedures described in section 553 of title 5, United States Code, for substantive rules (including notice and comment procedures).

''(3) The term 'covered Federal agency' means a Federal agency described in section 2801(c)(1).

''(4) The term 'Federal research projects' has the meaning indicated for such term in section 2801(b)(1).

''(5) The term 'Interagency Committee' has the meaning indicated for such term in section 2803(a).

''(6) The term 'Office' has the meaning indicated for such term in section 2801(a).''.

SEC. 3. CONFORMING PROVISIONS.

(a) REPEAL.—Section 491 of the Public Health Service Act (42 U.S.C. 289) is repealed.

(b) RULE OF CONSTRUCTION.—With respect to a covered Federal agency as defined in title XXVIII of the Public Health Service Act, as added by the amendment made by section 2—

(1) such amendment does not terminate any office or other administrative unit in such an agency that before the date of the enactment of this Act was established with respect to the protection of human subjects in research conducted, supported, or otherwise subject to regulation by the Federal Government; and

(2) on and after the date of the enactment of this Act such an office or unit has only such duties as may be assigned by the Director of the Office for Protection of Human Research Subjects under such title XXVIII, after consultation with the head of the agency within which the office or unit is established, and the Director may terminate the office or unit, after consultation with such agency head.

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