105TH CONGRESS
1ST SESSION

S. 193

To provide protections to individuals who are the human subject of research.

IN THE SENATE OF THE UNITED STATES

JANUARY 22, 1997

Mr. GLENN introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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A BILL

To provide protections to individuals who are the human subject of 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 1997''.

SEC. 2. FINDINGS AND PURPOSES.

(a) FINDINGS.—Congress makes the following findings:

(1) The Constitution guarantees the right of the people to be secure in their persons, and the Declaration of Independence asserts as self-evident

that all men have certain unalienable rights among these are life, liberty and the pursuit of happiness.

(2) The first principle of the Nuremberg code states that with respect to human research, the voluntary consent of the human subject is absolutely essential. The Nuremberg code further asserts that such consent must be competent, informed and comprehending.

(3) In 1974, the Department of Health, Education and Welfare published regulations (45 CFR 46) governing the protection of human subjects in research. These regulations applied only to research sponsored by the Department. In 1991 these regulations were adopted by 16 additional Federal agencies to apply to any research which these agencies may sponsor.

(4) Between 1974 and 1983, Congress enacted 2 Public Laws that established ethical advisory bodies. Public Law 91–348 established the National Commission for the Protection of Human Subjects of Biomedical Research and Public Law 95–622 established the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Each of these advisory bodies

made recommendations to the President and Congress to expand protections for human research subjects. Some of these recommendations have been incorporated into the Federal regulation (45 CFR 46).

(5) In 1995, the President's Advisory Committee on Human Radiation Experiments found that there are significant deficiencies in some aspects of the current system for the protection of human subjects. In particular, the Committee found that some consent forms currently in use are flawed in morally significant aspects.

(6) The President's Advisory Committee on Human Radiation Experiments recommended the adoption of a Federal policy requiring the informed consent of all human subjects of classified research and that this requirement not be subject to exemption or waiver. The Committee further recommended that in all cases, potential subjects should be informed of the identity of the sponsoring Federal agency and that the project involves classified information.

(7) Some agencies of the Federal government sponsor research involving human subjects, but these

agencies have not adopted the Common Rule as provided for in part 46 of title 45, Code of Federal Regulations.

(8) Private individuals or institutions that do not receive any Federal funding or that are not seeking the approval of the Food and Drug Administration for a drug or device, and that sponsor research involving human subjects, do not need to abide by the requirements of part 46 of title 45, Code of Federal Regulations.

(9) Many, but not all, research institutions that receive Federal sponsorship for research involving human subjects may voluntarily apply the protections of the Common Rule to all research conducted at the research institution.

(10) Notwithstanding paragraphs (1) through (9), no provision of United States law explicitly requires that informed consent and independent review of research involving human subject be obtained.

(11) The human research subject activities described in this section are either in interstate (or foreign) commerce or substantially affect such commerce or the free flow thereof, and the regulation of those activities as provided for in this Act is necessary to prevent and eliminate burdens upon such

commerce and to effectively regulate such commerce, in order to insure that the rights and welfare of human research subjects are protected.

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

(1) to apply common rule protections to all human subject research and provide for criminal sanctions for violations of this Act;

(2) to prohibit the provision of Federal support for classified research that is not reviewed by an institutional review board and require disclosure to human research subjects of certain information regarding classified research; and

(3) to address any potential regulatory conflict of interest within the Department of Health and Human Services and the National Institutes of Health, and establish an Office for Protection of Research Subjects within the Office of the Secretary of Health and Human Services.

SEC. 3. DEFINITIONS.

In this Act:

(1) ASSURANCE.—The term ''assurance'' means a written agreement between the Secretary and a research facility, or an institution supporting the research facility, that such research facility will comply with all Federal ethical standards regarding human

subject research, including the common rule protections. Such term includes a ''single project assurance'', ''multiple project assurance'', and ''cooperative project assurance''.

(2) BOARD.—The term ''board'' means an institutional review board established in accordance with and for the purposes expressed in this Act.

(3) CLASSIFIED RESEARCH.—The term ''classified research'' means research involving human subjects that is specifically authorized under criteria established by an Executive Order to be kept secret in the interest of national defense of foreign policy.

(4) COMMON RULE PROTECTIONS.—The term ''common rule protections'' means the requirements and protections provided under part 46 of title 45, Code of Federal Regulations, as in effect on the date of enactment of this Act.

(5) HUMAN SUBJECT.—The term ''human subject'' means a living individual about whom an investigator (whether professional or student) conducting research obtains—

(A) data through intervention or interaction with the individual; or

(B) individually identifiable private information.

(6) INTERSTATE COMMERCE.—The term ''interstate commerce'' has the meaning given the term in section 201(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(b)).

(7) OFFICE.—The term ''Office'' means the Office for Protection of Research Subjects established under section 102(a) or the Office designated under section 102(b).

(8) RESEARCH.—The term ''research'' means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge, and those activities for which a Federal department or agency has specific responsibility for regulating as research activities.

(9) RESEARCH FACILITY.—The term ''research facility'' means any public or private entity, agency (including Federal, State, and other agencies) or person that—

(A) uses human subjects in research involving interstate commerce; or

(B) receives support under a grant, loan, contract, or other award from a department, agency, or instrumentality of the United States

for the purpose of carrying out research using human subjects.

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

(11) STATE.—The term ''State'' means a State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, or any other territory or possession of the United States.

TITLE I—GENERAL RESEARCH REQUIREMENTS

SEC. 101. APPLICATION OF COMMON RULE REQUIREMENTS AND PROTECTIONS.

(a) IN GENERAL.—Except as provided in subsection (b), the requirements and protections provided under part 46 of title 45, Code of Federal Regulations, as in effect on the date of enactment of this Act, shall apply to research conducted by research facilities using human subjects.

(b) EXCEPTION WHEN IN CONFLICT WITH ACT.—The provisions of this Act shall supersede any provision of part 46 of title 45, Code of Federal Regulations, if such provisions are in conflict.

SEC. 102. OFFICE FOR PROTECTION OF RESEARCH SUBJECTS.

(a) ESTABLISHMENT.—Not later than 90 days after the date of enactment of this Act, the Secretary shall establish within the Office of the Secretary an office to be known as the ''Office for Protection of Human Research Subjects'' or make the designation described in subsection (b).

(b) DESIGNATION.—Not later than 90 days after the date of enactment of this Act, the Secretary may reassign the Office for Protection from Research Risks to the Office of the Secretary and designate such Office to carry out the duties of the Office under this Act.

(c) FUNDING.—The Secretary shall ensure the availability of such sums as may be necessary to enable the Office to conduct all activities under this Act, as well as to conduct appropriate oversight and implementation activities.

SEC. 103. REGISTRATION OF FACILITIES.

(a) IN GENERAL.—To conduct research using human subjects, a research facility shall have in effect a valid registration with the Secretary in accordance with this section and with such regulations as the Secretary may promulgate.

(b) REQUIREMENTS.—An application for registration under subsection (a) shall include—

(1) a statement of the principles of the applicant research facility with respect to the protection of the rights and welfare of humans subjects of research conducted or supported by the research facility;

(2) a designation of the official responsible for all human subject research conducted or supported by the applicant research facility;

(3) a designation of, and membership roster or rosters for, each board that is responsible for reviewing human subject research conducted or supported by the applicant research facility; and

(4) an assurance that the applicant research facility is complying and will continue to comply with the requirements for—

(A) board membership;

(B) the functions and operations of the board;

(C) the review of research by the board;

(D) the approval of research by the board;

(E) the suspension or termination of board approval of research;

(F) the maintenance of records by the board; and

(G) obtaining and documenting informed consent from human subjects, consent from children, and permission from parents or guardians as provided for in the common rule protections.

(c) PERIOD OF REGISTRATION.—The registration of a research facility shall be valid for the 3-year period beginning on the date on which the Secretary approves the application for registration, except that such registration may be suspended, revoked or deemed to be incomplete or otherwise insufficient by the Secretary.

(d) AFFECT OF ASSURANCES.—Upon the notification of the Secretary by the official designated under subsection (b)(2), a research facility shall be deemed to be in compliance with the registration provisions of this section, if that research facility has in effect a valid assurance negotiated with the Department of Health and Human Services.

(e) FAILURE TO REGISTER.—A research facility may not conduct an activity covered by this Act if the facility is not registered with the Secretary under this section or an assurance described in subsection (d) is not in effect.

SEC. 104. INSPECTION AND INVESTIGATION.

(a) IN GENERAL.—The Secretary may carry out such inspections or investigations as may be necessary to enable

the Secretary to determine whether any research facility has violated or is violating any provision of this Act.

(b) ACCESS TO FACILITIES AND RECORDS.—To enable the Secretary to carry out subsection (a), the Secretary shall, after providing reasonable notice, be provided with access to a research facility and the records required to be kept by the facility pursuant to section 103(b)(4) and the common rule protections.

(c) PENALTIES.—Title 18, United States Code, is amended by inserting after chapter 89 the following:

"CHAPTER 90—PROTECTION OF HUMAN SUBJECTS BY RESEARCH FACILITIES

"§ 1841. Protection of human subjects

''(a) IN GENERAL.—Whoever forcibly assaults, resists, opposes, impedes, intimidates, or interferes with any person while such person is engaged in the performance of his or her official duties under the Human Research Subject Protections Act of 1997, or because such person has carried out such duties, shall be fined not more than $10,000, or imprisoned not more than 3 years, or both.

''(b) USE OF WEAPON.—Whoever in the commission of an act that is a violation of subsection (a), uses a deadly or dangerous weapon shall be fined not more than $25,000, or imprisoned not more than 10 years, or both.

''(c) HOMICIDE.—Whoever kills any human being while that human being is engaged in the performance of his or her official duties under the Human Research Subject Protections Act of 1997, or because such human being has carried out such duties, shall be fined or imprisoned as provided for under sections 1111 and 1114.''.

SEC. 105. ENFORCEMENT.

(a) SUSPENSION OF REGISTRATION.—If the Secretary has reason to believe that any research facility registered under section 103 has violated or is in violation of any provision of this Act, or of any of the rules or regulations or standards promulgated by the Secretary under this Act, the Secretary may suspend the registration of that research facility for a period of not to exceed 30 days, and after notice and opportunity for a hearing, may suspend such registration for any additional period as the Secretary may determine appropriate. Upon a determination by the Secretary that such a violation has occurred the Secretary may continue such suspension or revoke the registration.

(b) PENALTIES.—Any employee of a research facility that knowingly violates any provision of this Act shall, on conviction thereof, shall be fined not more than $10,000,

or imprisoned not more than 3 years, or both. Such violation shall be referred by the Secretary to the United States Department of Justice for prosecution.

SEC. 106. REGULATIONS.

The Secretary may promulgate such regulations as the Secretary determines to be necessary to carry out this Act.

TITLE II—CLASSIFIED RESEARCH

SEC. 201. PROHIBITION.

Notwithstanding any other provision of law, no Federal funds shall be expended for the conduct of any classified research where a board has waived informed consent as defined in the common rule protections or where a determination has been made that the research is exempt from review by such a board.

SEC. 202. ADDITIONAL REQUIREMENTS.

In addition to the requirements applicable under the common rule protections, the human subjects involved in any classified research that receives Federal funding shall be provided with the following additional information:

(1) The identity of the Federal agency providing funds in connection with the conduct of such research.

(2) A statement that the research involves classified information.

(3) An unclassified description of the purpose of the research.

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