

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

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Human Research Sub-
5 ject Protections Act of 1997”.

6 **SEC. 2. FINDINGS AND PURPOSES.**

7 (a) FINDINGS.—Congress makes the following find-
8 ings:

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

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

3 (2) The first principle of the Nuremberg code
4 states that with respect to human research, the vol-
5 untary consent of the human subject is absolutely
6 essential. The Nuremberg code further asserts that
7 such consent must be competent, informed and com-
8 prehending.

9 (3) In 1974, the Department of Health, Edu-
10 cation and Welfare published regulations (45 CFR
11 46) governing the protection of human subjects in
12 research. These regulations applied only to research
13 sponsored by the Department. In 1991 these regula-
14 tions were adopted by 16 additional Federal agencies
15 to apply to any research which these agencies may
16 sponsor.

17 (4) Between 1974 and 1983, Congress enacted
18 2 Public Laws that established ethical advisory bod-
19 ies. Public Law 91-348 established the National
20 Commission for the Protection of Human Subjects
21 of Biomedical Research and Public Law 95-622 es-
22 tablished the President's Commission for the Study
23 of Ethical Problems in Medicine and Biomedical and
24 Behavioral Research. Each of these advisory bodies

1 made recommendations to the President and Con-
2 gress to expand protections for human research sub-
3 jects. Some of these recommendations have been in-
4 corporated into the Federal regulation (45 CFR 46).

5 (5) In 1995, the President's Advisory Commit-
6 tee on Human Radiation Experiments found that
7 there are significant deficiencies in some aspects of
8 the current system for the protection of human sub-
9 jects. In particular, the Committee found that some
10 consent forms currently in use are flawed in morally
11 significant aspects.

12 (6) The President's Advisory Committee on
13 Human Radiation Experiments recommended the
14 adoption of a Federal policy requiring the informed
15 consent of all human subjects of classified research
16 and that this requirement not be subject to exemp-
17 tion or waiver. The Committee further recommended
18 that in all cases, potential subjects should be in-
19 formed of the identity of the sponsoring Federal
20 agency and that the project involves classified infor-
21 mation.

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

1 agencies have not adopted the Common Rule as pro-
2 vided for in part 46 of title 45, Code of Federal
3 Regulations.

4 (8) Private individuals or institutions that do
5 not receive any Federal funding or that are not
6 seeking the approval of the Food and Drug Adminis-
7 tration for a drug or device, and that sponsor re-
8 search involving human subjects, do not need to
9 abide by the requirements of part 46 of title 45,
10 Code of Federal Regulations.

11 (9) Many, but not all, research institutions that
12 receive Federal sponsorship for research involving
13 human subjects may voluntarily apply the protec-
14 tions of the Common Rule to all research conducted
15 at the research institution.

16 (10) Notwithstanding paragraphs (1) through
17 (9), no provision of United States law explicitly re-
18 quires that informed consent and independent review
19 of research involving human subject be obtained.

20 (11) The human research subject activities de-
21 scribed in this section are either in interstate (or
22 foreign) commerce or substantially affect such com-
23 merce or the free flow thereof, and the regulation of
24 those activities as provided for in this Act is nec-
25 essary to prevent and eliminate burdens upon such

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

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

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

8 (2) to prohibit the provision of Federal support
9 for classified research that is not reviewed by an in-
10 stitutional review board and require disclosure to
11 human research subjects of certain information re-
12 garding classified research; and

13 (3) to address any potential regulatory conflict
14 of interest within the Department of Health and
15 Human Services and the National Institutes of
16 Health, and establish an Office for Protection of Re-
17 search Subjects within the Office of the Secretary of
18 Health and Human Services.

19 **SEC. 3. DEFINITIONS.**

20 In this Act:

21 (1) ASSURANCE.—The term “assurance” means
22 a written agreement between the Secretary and a re-
23 search facility, or an institution supporting the re-
24 search facility, that such research facility will comply
25 with all Federal ethical standards regarding human

1 subject research, including the common rule protec-
2 tions. Such term includes a “single project assur-
3 ance”, “multiple project assurance”, and “coopera-
4 tive project assurance”.

5 (2) BOARD.—The term “board” means an insti-
6 tutional review board established in accordance with
7 and for the purposes expressed in this Act.

8 (3) CLASSIFIED RESEARCH.—The term “classi-
9 fied research” means research involving human sub-
10 jects that is specifically authorized under criteria es-
11 tablished by an Executive Order to be kept secret in
12 the interest of national defense or foreign policy.

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

18 (5) HUMAN SUBJECT.—The term “human sub-
19 ject” means a living individual about whom an inves-
20 tigator (whether professional or student) conducting
21 research obtains—

22 (A) data through intervention or inter-
23 action with the individual; or

24 (B) individually identifiable private infor-
25 mation.

1 (6) INTERSTATE COMMERCE.—The term “inter-
2 state commerce” has the meaning given the term in
3 section 201(b) of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 321(b)).

5 (7) OFFICE.—The term “Office” means the Of-
6 fice for Protection of Research Subjects established
7 under section 102(a) or the Office designated under
8 section 102(b).

9 (8) RESEARCH.—The term “research” means a
10 systematic investigation, including research develop-
11 ment, testing and evaluation, designed to develop or
12 contribute to generalizable knowledge, and those ac-
13 tivities for which a Federal department or agency
14 has specific responsibility for regulating as research
15 *activities*.

16 (9) RESEARCH FACILITY.—The term “research
17 facility” means any public or private entity, agency
18 (including Federal, State, and other agencies) or
19 person that—

20 (A) uses human subjects in research in-
21 volving interstate commerce; or

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

1 for the purpose of carrying out research using
2 human subjects.

3 (10) SECRETARY.—The term “Secretary”
4 means the Secretary of Health and Human Services.

5 (11) STATE.—The term “State” means a State
6 of the United States, the District of Columbia, the
7 Commonwealth of Puerto Rico, the Virgin Islands,
8 Guam, American Samoa, or any other territory or
9 possession of the United States.

10 **TITLE I—GENERAL RESEARCH** 11 **REQUIREMENTS**

12 **SEC. 101. APPLICATION OF COMMON RULE REQUIREMENTS** 13 **AND PROTECTIONS.**

14 (a) IN GENERAL.—Except as provided in subsection
15 (b), the requirements and protections provided under part
16 46 of title 45, Code of Federal Regulations, as in effect
17 on the date of enactment of this Act, shall apply to re-
18 search conducted by research facilities using human sub-
19 jects.

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

1 **SEC. 102. OFFICE FOR PROTECTION OF RESEARCH SUB-**
2 **JECTS.**

3 (a) ESTABLISHMENT.—Not later than 90 days after
4 the date of enactment of this Act, the Secretary shall es-
5 tablish within the Office of the Secretary an office to be
6 known as the “Office for Protection of Human Research
7 Subjects” or make the designation described in subsection
8 (b).

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

14 (c) FUNDING.—The Secretary shall ensure the avail-
15 ability of such sums as may be necessary to enable the
16 Office to conduct all activities under this Act, as well as
17 to conduct appropriate oversight and implementation ac-
18 tivities.

19 **SEC. 103. REGISTRATION OF FACILITIES.**

20 (a) IN GENERAL.—To conduct research using human
21 subjects, a research facility shall have in effect a valid reg-
22 istration with the Secretary in accordance with this section
23 and with such regulations as the Secretary may promul-
24 gate.

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

1 (1) a statement of the principles of the appli-
2 cant research facility with respect to the protection
3 of the rights and welfare of humans subjects of re-
4 search conducted or supported by the research facil-
5 ity;

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

9 (3) a designation of, and membership roster or
10 rosters for, each board that is responsible for review-
11 ing human subject research conducted or supported
12 by the applicant research facility; and

13 (4) an assurance that the applicant research fa-
14 cility is complying and will continue to comply with
15 the requirements for—

16 (A) board membership;

17 (B) the functions and operations of the
18 board;

19 (C) the review of research by the board;

20 (D) the approval of research by the board;

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

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

1 (G) obtaining and documenting informed
2 consent from human subjects, consent from
3 children, and permission from parents or guard-
4 ians as provided for in the common rule protec-
5 tions.

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

12 (d) AFFECT OF ASSURANCES.—Upon the notification
13 of the Secretary by the official designated under sub-
14 section (b)(2), a research facility shall be deemed to be
15 in compliance with the registration provisions of this sec-
16 tion, if that research facility has in effect a valid assurance
17 negotiated with the Department of Health and Human
18 Services.

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

23 **SEC. 104. INSPECTION AND INVESTIGATION.**

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

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

3 (b) ACCESS TO FACILITIES AND RECORDS.—To en-
4 able the Secretary to carry out subsection (a), the Sec-
5 retary shall, after providing reasonable notice, be provided
6 with access to a research facility and the records required
7 to be kept by the facility pursuant to section 103(b)(4)
8 and the common rule protections.

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

11 **“CHAPTER 90—PROTECTION OF HUMAN**
12 **SUBJECTS BY RESEARCH FACILITIES**

13 **“§ 1841. Protection of human subjects**

14 “(a) IN GENERAL.—Whoever forcibly assaults, re-
15 sists, opposes, impedes, intimidates, or interferes with any
16 person while such person is engaged in the performance
17 of his or her official duties under the Human Research
18 Subject Protections Act of 1997, or because such person
19 has carried out such duties, shall be fined not more than
20 \$10,000, or imprisoned not more than 3 years, or both.

21 “(b) USE OF WEAPON.—Whoever in the commission
22 of an act that is a violation of subsection (a), uses a deadly
23 or dangerous weapon shall be fined not more than
24 \$25,000, or imprisoned not more than 10 years, or both.

1 “(c) HOMICIDE.—Whoever kills any human being
 2 while that human being is engaged in the performance of
 3 his or her official duties under the Human Research Sub-
 4 ject Protections Act of 1997, or because such human being
 5 has carried out such duties, shall be fined or imprisoned
 6 as provided for under sections 1111 and 1114.”.

7 **SEC. 105. ENFORCEMENT.**

8 (a) SUSPENSION OF REGISTRATION.—If the Sec-
 9 retary has reason to believe that any research facility reg-
 10 istered under section 103 has violated or is in violation
 11 of any provision of this Act, or of any of the rules or regu-
 12 lations or standards promulgated by the Secretary under
 13 this Act, the Secretary may suspend the registration of
 14 that research facility for a period of not to exceed 30 days,
 15 and after notice and opportunity for a hearing, may sus-
 16 pend such registration for any additional period as the
 17 Secretary may determine appropriate. Upon a determina-
 18 tion by the Secretary that such a violation has occurred
 19 the Secretary may continue such suspension or revoke the
 20 registration.

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

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

4 **SEC. 106. REGULATIONS.**

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

8 **TITLE II—CLASSIFIED**
 9 **RESEARCH**

10 **SEC. 201. PROHIBITION.**

11 Notwithstanding any other provision of law, no Fed-
 12 eral funds shall be expended for the conduct of any classi-
 13 fied research where a board has waived informed consent
 14 as defined in the common rule protections or where a de-
 15 termination has been made that the research is exempt
 16 from review by such a board.

17 **SEC. 202. ADDITIONAL REQUIREMENTS.**

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

22 (1) *The identity of the Federal agency provid-*
 23 *ing funds in connection with the conduct of such re-*
 24 *search.*



- 1 (2) A statement that the research involves clas-
- 2 sified information.
- 3 (3) An unclassified description of the purpose
- 4 of the research.

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