

106TH CONGRESS
2D SESSION

H. R. 4605

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

IN THE HOUSE OF REPRESENTATIVES

JUNE 8, 2000

Ms. DEGETTE (for herself, Mr. MICA, Mr. WAXMAN, Mr. DINGELL, Mr. BROWN of Ohio, Mr. LATOURETTE, Mr. TOWNS, Mr. STARK, and Mr. KUCINICH) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Public Health Service Act with respect to the protection of human subjects in 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 2000”.

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

7 (a) FINDINGS.—The Congress finds as follows:

8 (1) The first principle of the Nuremberg code
9 states that with respect to human research, the vol-

1 untary consent of the human subject is absolutely
2 essential. The Nuremberg code further asserts that
3 such consent must be competent, informed and com-
4 prehending.

5 (2) In 1974, the Department of Health, Edu-
6 cation and Welfare published regulations (45 CFR
7 46) governing the protection of human subjects in
8 research. These regulations applied only to research
9 sponsored by the Department. In 1991, subpart A of
10 these regulations was adopted by 16 additional Fed-
11 eral agencies to apply to any research which these
12 agencies may conduct or sponsor.

13 (3) Between 1974 and 1983, Congress enacted
14 two Public Laws that established ethical advisory
15 bodies. Public Law 91–348 established the National
16 Commission for the Protection of Human Subjects
17 of Biomedical and Behavioral Research and Public
18 Law 95–622 established the President’s Commission
19 for the Study of Ethical Problems in Medicine and
20 Biomedical and Behavioral Research. Each of these
21 advisory bodies made recommendations to the Presi-
22 dent and Congress to expand protections for human
23 research subjects. Some of these recommendations
24 have been incorporated into the Federal regulation
25 (45 CFR 46).

1 (4) In 1995, the President’s Advisory Com-
2 mittee on Human Radiation Experiments found that
3 there are significant deficiencies in some aspects of
4 the current system for the protection of human sub-
5 jects. In particular, the Committee found that some
6 consent forms currently in use are flawed in morally
7 significant aspects.

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

18 (6) In 1996, Congress enacted the Health In-
19 surance Portability and Accountability Act, which
20 established an August 21, 1999, deadline to enact
21 comprehensive health privacy rules. Failure to meet
22 that deadline triggered a requirement for the Sec-
23 retary of Health and Human Services to issue final
24 health privacy regulations by February 2000.

1 (7) In 1998 and 2000, the Department of
2 Health and Human Services’s Inspector General
3 found that the effectiveness of Institutional Review
4 Board was “in jeopardy” and attention needed to be
5 directed to enhancing human subject protections for
6 a widening scope of clinical investigation.

7 (8) In 1998 and 1999, the National Bioethics
8 Advisory Commission found that Federal protections
9 do not always contain specific protections for certain
10 vulnerable populations and that existing regulations
11 do not adequately address issues involving human bi-
12 ological materials.

13 (9) Some agencies of the Federal government
14 sponsor research involving human subjects, but these
15 agencies have not adopted the Common Rule or vul-
16 nerable-populations protections as provided for in
17 part 46 of title 45, Code of Federal Regulations,
18 specifically subparts B, C, and D.

19 (10) Private individuals or institutions that do
20 not receive any Federal funding or that are not
21 seeking the approval of the Food and Drug Adminis-
22 tration for a drug, device, or biologic and that spon-
23 sor research involving human subjects, do not need
24 to abide by the requirements of part 46 of title 45,
25 Code of Federal Regulations.

1 (11) Research institutions that receive Federal
2 funds for conducting research involving human sub-
3 jects are not required to apply the protections of
4 part 46 of title 45, Code of Federal Regulations, to
5 all research conducted at the institution. Many, but
6 not all, research institutions have voluntarily made
7 this commitment.

8 (12) Notwithstanding paragraphs (1) through
9 (8), no provision of United States law explicitly re-
10 quires that informed consent and independent review
11 of all research involving human subjects be obtained.

12 (13) The human research subject activities de-
13 scribed in this section are either in interstate (or
14 foreign) commerce or substantially affect such com-
15 merce or the free flow thereof, and the regulation of
16 those activities as provided for in this Act is nec-
17 essary to prevent and eliminate burdens upon such
18 commerce and to effectively regulate such commerce,
19 in order to insure that the rights and welfare of
20 human research subjects are protected.

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

22 (1) to apply Common Rule and vulnerable-pop-
23 ulations protections to all human research subjects
24 independent of setting and funding source;

1 (2) to prohibit the provision of Federal support
2 for classified research that is not approved by an in-
3 stitutional review board and require disclosure to
4 human research subjects of certain information re-
5 garding classified research; and

6 (3) to enhance regulatory oversight of human
7 subject research by formally establishing an Office
8 for Protection of Research Subjects within the Office
9 of the Secretary of Health and Human Services.

10 **TITLE I—HUMAN SUBJECT** 11 **PROTECTIONS**

12 **SEC. 101. PROTECTION OF HUMAN SUBJECTS IN RE-** 13 **SEARCH; UNIFORM NATIONAL APPLICA-** 14 **BILITY OF COMMON RULE AND PROVISIONS** 15 **PROTECTING VULNERABLE POPULATIONS.**

16 Part H of title IV of the Public Health Service Act
17 (42 U.S.C. 289 et seq.) is amended by inserting after sec-
18 tion 491 the following section:

19 “PROTECTION OF HUMAN SUBJECTS; UNIFORM NATIONAL
20 APPLICABILITY OF COMMON RULE AND PROVISIONS
21 PROTECTING VULNERABLE POPULATIONS

22 “SEC. 491A. (a) IN GENERAL.—All human-subject
23 research shall be conducted in accordance with the provi-
24 sions of subpart A of part 46 of title 45, Code of Federal
25 Regulations (referred to in this section as the ‘common
26 rule’), and as applicable to the human subjects used in

1 such research, with the provisions of subparts B through
2 D of such part 46 (referred to in this section as ‘vulner-
3 able-populations rules’), except to the extent that such
4 provisions are in conflict with this section.

5 “(b) DEFINITIONS.—

6 “(1) HUMAN-SUBJECT RESEARCH.—For pur-
7 poses of this section, the term ‘human-subject re-
8 search’ means research that is conducted with one or
9 more human subjects and—

10 “(A) is conducted, supported, or otherwise
11 subject to regulation under a provision of Fed-
12 eral law (other than this section), without re-
13 gard to whether the Federal agency that admin-
14 isters such law has taken administrative action
15 to make the common rule applicable to the
16 agency; or

17 “(B) is not described in subparagraph (A)
18 and has activities that are in or that affect
19 interstate commerce.

20 “(2) OTHER DEFINITIONS.—For purposes of
21 this section:

22 “(A) The term ‘common rule’ has the
23 meaning indicated for such term in subsection
24 (a).

1 “(B) The term ‘Federal agency’ has the
2 meaning given the term ‘Executive agency’ in
3 section 105 of title 5, United States Code.

4 “(C) The term ‘human subject’ has the
5 meaning given such term in section 46.102 of
6 title 45, Code of Federal Regulations.

7 “(D) The term ‘research’ has the meaning
8 given such term in section 46.102 of title 45,
9 Code of Federal Regulations.

10 “(E) The term ‘vulnerable-populations
11 rules’ has the meaning indicated for such term
12 in subsection (a).”.

13 **SEC. 102. SCOPE OF AUTHORITY OF SECRETARY.**

14 Section 491A of the Public Health Service Act, as
15 added by section 101 of this Act, is amended by adding
16 at the end the following subsections:

17 “(c) SCOPE OF AUTHORITY OF SECRETARY.—

18 “(1) IN GENERAL.—The common rule (includ-
19 ing the exemptions described in section 46.101(b) of
20 title 45, Code of Federal Regulations) and the vul-
21 nerable-populations rules, as in effect on the day be-
22 fore the date of the enactment of the Human Re-
23 search Subject Protections Act of 2000, continue to
24 be in effect on and after such date, subject to para-
25 graph (2).

1 “(2) MODIFICATIONS.—

2 “(A) IN GENERAL.—This section may not
3 be construed as affecting the authority of the
4 Secretary to modify the provisions of the com-
5 mon rule or the vulnerable-populations rules,
6 except to the extent that any such modification
7 is in conflict with this section. Any such modi-
8 fication shall be made by regulation.

9 “(B) AGENCY-SPECIFIC ADDITIONAL PRO-
10 TECTIONS.—With respect to human-subject re-
11 search that is conducted, supported, or other-
12 wise subject to regulation under a provision of
13 Federal law (other than this section), the Sec-
14 retary may under subparagraph (A) permit the
15 Federal agency involved to establish additional
16 protections for the protection of human subjects
17 if the Secretary determines that such additional
18 protections are not in conflict with protections
19 established under this section.

20 “(3) SUSPENSION AND REVOCATION.—After
21 providing notice and an opportunity for a hearing,
22 the Secretary may suspend or revoke the registra-
23 tion, impose restrictions during a corrective action
24 period, or withhold Federal funding to an Institu-

1 tional Review Board described under subsection
2 (e)(1)(F).

3 **SEC. 103. ENHANCED HUMAN SUBJECT PROTECTIONS FOR**
4 **PEOPLE WITH DIMINISHED DECISIONMAKING**
5 **CAPACITY.**

6 Not later than 180 days after the date of the enact-
7 ment of this Act, the Secretary of Health and Human
8 Services shall, for purposes of section 491A of the Public
9 Health Service Act, promulgate regulations to enhance the
10 protection of people with diminished decisionmaking ca-
11 pacity with respect to their participation as subjects in
12 clinical research.

13 **TITLE II—INFORMED CONSENT**

14 **SEC. 201. RIGHT OF INFORMED CONSENT.**

15 Section 491A of the Public Health Service Act, as
16 added by section 102 of this Act, is amended by adding
17 at the end the following subsection:

18 “(d) RIGHT OF INFORMED CONSENT.—

19 “(1) IN GENERAL.—Except as provided by the
20 Secretary by regulation, no investigator may involve
21 a living human being as a subject in research unless
22 the investigator has obtained the legally effective in-
23 formed consent of the subject or the subject’s legally
24 authorized representative.

1 “(2) DISCLOSURE AND UNDERSTANDING.—
2 During the informed consent process, all human
3 subjects shall be given full and complete information
4 relevant to the proposed research in language and in
5 a manner that allows them to understand the infor-
6 mation and make an informed decision, free of coer-
7 cion, regarding their participation in research. An
8 individual knowledgeable about the proposed re-
9 search must provide this information such that any
10 questions the potential subject has can be answered.

11 “(3) CONSENT FORM.—A human subject of re-
12 search shall be given a consent form that includes,
13 at a minimum, the basic elements of informed con-
14 sent, including the purpose of the study, the poten-
15 tial risks, benefits and alternatives to participation,
16 the distinction between research and therapeutic
17 treatment, the right to withdraw participation at any
18 time, investigator financial interest under paragraph
19 (4)(B), and the sponsor of the study. A copy of the
20 signed consent form shall be given to the human
21 subject and contact information for the Office for
22 Protection of Research Subjects for questions or to
23 report concerns.”.

1 **SEC. 202. WRITTEN ATTESTATION AND DISCLOSURE.**

2 Section 491A(d) of the Public Health Service Act, as
3 added by section 201 of this Act, is amended by adding
4 at the end the following paragraph:

5 “(4) WRITTEN ATTESTATION AND DISCLO-
6 SURE.—

7 “(A) IN GENERAL.—An investigator en-
8 gaged in research involving human subjects
9 shall file a written attestation of familiarity
10 with and agreement to comply with the require-
11 ments of human subject research protections,
12 including informed consent.

13 “(B) FINANCIAL INTEREST.—An investi-
14 gator engaged in research involved in human
15 subjects shall disclose to the subjects investi-
16 gator financial interest in the research, includ-
17 ing capitation payments, disclosure of sponsors
18 of the research and any conflict deemed nec-
19 essary by the Institutional Review Board.”.

20 **TITLE III—INSTITUTIONAL**
21 **REVIEW BOARDS**

22 **SEC. 301. REQUIREMENTS FOR BOARD.**

23 Section 491A of the Public Health Service Act, as
24 added by section 201 of this Act, is amended by adding
25 at the end the following subsection:

26 “(e) INSTITUTIONAL REVIEW BOARDS.—

1 “(1) REQUIREMENTS FOR BOARDS.—Human-
2 subject research may not be conducted unless an In-
3 stitutional Review Board established pursuant to
4 this section has, for purposes of the common rule
5 (and the vulnerable-populations rules, as applicable),
6 approved the proposal for such research. The ap-
7 proval by the Board of the proposal for the research
8 is not effective unless, in addition to conditions es-
9 tablished by the Secretary, the following conditions
10 are met:

11 “(A) Of the membership of such Board:

12 “(i) Not fewer than 2 members or 20
13 percent of all members (whichever is great-
14 er) are individuals whose primary expertise
15 is in scientific areas.

16 “(ii) Not fewer than 2 members or 20
17 percent of all members (whichever is great-
18 er) are individuals whose primary expertise
19 is in nonscientific areas.

20 “(iii) Not fewer than 2 members or
21 20 percent of all members (whichever is
22 greater) are individuals who are not affili-
23 ated with the institution with respect to
24 which the Board is established (other than
25 by serving on the Board), who are not im-

1 mediate family members of any individual
2 who is affiliated with the institution, and
3 who do not have a conflict of interest (in-
4 cluding nonproprietary interest).

5 “(B) When reviewing a proposal that will
6 include as a subject an individual who is a
7 member of a vulnerable population, the Board
8 shall include members who are experts in the
9 issues involving such population. Such members
10 shall be allowed to fully participate in the
11 Board review process and have the same voting
12 rights as other Board members.

13 “(C) With respect to the review by the
14 Board of a proposal for human-subject re-
15 search, the Board does not consider a quorum
16 to have been established for a meeting unless
17 the members present at the meeting include one
18 or more members who are individuals described
19 in clauses (i) and (ii) of subparagraph (A) and
20 one or more members who are individuals de-
21 scribed in clause (iii) of such subparagraph.

22 “(D) The institution with respect to which
23 the Board is employed by ensures that the
24 Board has an orientation and continuing edu-
25 cation program for new members of the Board,

1 and with respect to ethical matters that relate
2 to research, a continuing education program for
3 all members of the Board.

4 “(E) The institution with respect to which
5 the Board is employed by is in compliance with
6 such conditions as the Secretary may by regula-
7 tion establish for purposes of ensuring that the
8 institution is providing to the Board and recov-
9 ering resources from the research sponsor suffi-
10 cient to carry out the responsibilities of the
11 Board pursuant to this section.

12 “(F) The Board has submitted to the Sec-
13 retary a registration informing the Secretary of
14 the existence of the Board, and the registration
15 was is in such form, was made in such manner,
16 and contained such agreements, assurances,
17 and information as the Secretary requested re-
18 garding functions of the Board under this sec-
19 tion.

20 “(G) The Board has submitted to the Sec-
21 retary such reports regarding the Board as the
22 Secretary has requested.”.

1 **SEC. 302. NOTIFICATION OF INSTITUTIONAL REVIEW**
2 **BOARD.**

3 Section 491A(e) of the Public Health Service Act, as
4 added by section 301 of this Act, is amended by adding
5 at the end the following paragraph:

6 “(2) NOTIFICATION OF INSTITUTIONAL REVIEW
7 BOARD.—In submitting to an Institutional Review
8 Board a proposal for human-subject research, the
9 sponsors and investigators for the research shall no-
10 tify the Board—

11 “(A) whether the proposal has been sub-
12 mitted to any other Institutional Review Board;

13 “(B) as applicable, of the findings of the
14 review made by such other Board, to the extent
15 the findings are available; and

16 “(C) whether the sponsors, investigators,
17 or institutions have been disqualified or re-
18 stricted by any Federal entity in their ability to
19 participate in human subject research, or are
20 ineligible to receive investigational new drugs,
21 or have agreed to some restriction.”.

22 **SEC. 303. ACTIVITIES.**

23 Section 491A(e) of the Public Health Service Act, as
24 amended by section 302 of this Act, is amended by adding
25 at the end the following subparagraph:

26 “(3) ACTIVITIES.—

1 “(A) DATA COLLECTION.—An Institutional
2 Review Board shall compile annual data on the
3 number of new research proposals reviewed, the
4 number of continuing research projects re-
5 viewed, the number of human subjects involved
6 in approved research, and other information to
7 be determined by the Secretary, and report
8 such data to the Office for Protection of Re-
9 search Subjects.

10 “(B) IMPROVED MONITORING.—The Sec-
11 retary shall promulgate regulations regarding
12 data safety and monitoring boards and clinical
13 trial monitoring plans. Such regulations shall
14 specify minimum reporting requirements to In-
15 stitutional Review Boards and the Office for
16 Protection of Research Subjects.

17 “(C) MULTIPLE SITE RESEARCH.—The
18 Secretary shall promulgate regulations regard-
19 ing the conduct of research at multiple research
20 sites, including international sites. Such regula-
21 tions shall specify minimum reporting require-
22 ments to Institutional Review Boards and the
23 Office for Protection of Research Subjects, con-
24 ditions requiring the establishment of data safe-
25 ty and monitoring boards, and other require-

1 ments necessary to assure compliance with this
2 section.”.

3 **SEC. 304. DISCLOSURE OF INTERESTS.**

4 Section 491A(e) of the Public Health Service Act, as
5 amended by section 303 of this Act, is amended by adding
6 at the end the following paragraph:

7 “(4)(A) All researchers shall disclose to an In-
8 stitutional Review Board any actual, perceived, or
9 potential conflicts of interest. All researchers shall
10 disclose to potential subjects financial interests they
11 have in research for which the subjects are being re-
12 cruited, including capitation payments, disclosure of
13 sponsors of the research and any conflict deemed
14 necessary by the Institutional Review Board.

15 “(B) All Board members shall disclose any ac-
16 tual, perceived, or potential conflicts of interest to
17 the Board, including but not limited to—

18 “(i) involvement as researchers in research
19 projects being reviewed by the Board;

20 “(ii) ownership interests in the research
21 projects being reviewed by the Board; and,

22 “(iii) financial relationships or arrange-
23 ments with private sponsors of research projects
24 being reviewed by the Board and provide that

1 information to the Office for Protection of Re-
2 search Subjects.

3 “(C) No Board member may participate in the
4 review of any research protocol under consideration
5 by the Board in which the member has a conflict of
6 interest (including nonproprietary interest).”.

7 **SEC. 305. ACCREDITATION.**

8 (a) IN GENERAL.—Section 491A(e)(1) of the Public
9 Health Service Act, as added by section 301 of this Act,
10 is amended by adding at the end the following subpara-
11 graph:

12 “(H)(i) Effective two years after the date
13 of the enactment of the Human Research Sub-
14 ject Protections Act of 2000, the Board has
15 been accredited by a nonprofit private entity
16 approved by the Secretary for purposes of this
17 subparagraph.”.

18 (b) REQUIREMENTS OF ACCREDITING BODY.—Sec-
19 tion 491A(e)(1)(H) of the Public Health Service Act, as
20 added by subsection (a) of this section, is amended by add-
21 ing at the end the following clauses:

22 “(ii) The accrediting body must meet
23 standards for accreditation established by the
24 Secretary.

1 “(iii) The accrediting body shall provide
2 satisfactory assurances that it will comply with
3 such standards.

4 “(iv) The Secretary shall evaluate annually
5 the performance of the accrediting body.

6 “(v) The Secretary may withdraw approval
7 of the accrediting body if the Secretary deter-
8 mines that the accrediting body does not meet
9 the standards under clause (ii).”.

10 **SEC. 306. COST RECOVERY.**

11 Section 491A(e) of the Public Health Service Act, as
12 amended by section 304 of this Act, is amended by adding
13 at the end the following paragraph:

14 “(5) COST RECOVERY.—Institutions may re-
15 cover costs associated with compliance for human
16 subject protections under this Act from government
17 sponsors of research as direct costs.”.

18 **SEC. 307. APPLICABILITY OF REQUIREMENTS.**

19 Section 491A of the Public Health Service Act, as
20 amended by section 301 of this Act, is amended by adding
21 at the end the following subsection:

22 “(f) APPLICABILITY OF REQUIREMENTS.—The re-
23 quirements of this section apply on and after the date of
24 the enactment of the Human Research Subject Protec-
25 tions Act of 2000.”.

1 **TITLE IV—FEDERAL OVERSIGHT**

2 **SEC. 401. ESTABLISHMENT OF OFFICE FOR PROTECTION**
3 **OF RESEARCH SUBJECTS.**

4 (a) IN GENERAL.—Section 491 of the Public Health
5 Service Act (42 U.S.C. 289) is amended—

6 (1) by redesignating subsection (b) as sub-
7 section (c);

8 (2) by striking “SEC. 491. (a) The Secretary
9 shall by regulation require” and inserting the fol-
10 lowing:

11 “(b) REQUIREMENT REGARDING INSTITUTIONAL RE-
12 VIEW BOARDS.—The Secretary shall by regulation re-
13 quire”; and

14 (3) by inserting before subsection (b) (as redес-
15 igned by paragraph (2) of this subsection) the fol-
16 lowing:

17 “SEC. 491. (a) OFFICE FOR PROTECTION OF RE-
18 SEARCH SUBJECTS.—There is established within the Of-
19 fice of the Secretary an office to be known as the Office
20 for Protection of Research Subjects (in this section re-
21 ferred to as the ‘Office’). The Office shall be headed by
22 a director, who shall be appointed by the Secretary. The
23 Secretary shall carry out this section acting through the
24 Director of the Office.”.

1 (b) CONFORMING AMENDMENTS.—Section 491 of the
2 Public Health Service Act (42 U.S.C. 289) is amended
3 in subsection (c) (as redesignated by subsection (a)(1) of
4 this section)—

5 (1) by striking “(c)(1) The Secretary shall” and
6 inserting the following:

7 “(c) ETHICS GUIDANCE PROGRAM.—

8 “(1) IN GENERAL.—The Secretary shall”; and

9 (2) by striking “(2) The Secretary shall” and
10 inserting the following:

11 “(2) PROCESS REGARDING VIOLATIONS.—The
12 Secretary shall”.

13 **SEC. 402. AUTHORIZATION OF APPROPRIATIONS.**

14 Section 491 of the Public Health Service Act (42
15 U.S.C. 289), as amended by section 401 of this Act, is
16 amended by adding at the end the following subsection:

17 “(d) AUTHORIZATION OF APPROPRIATIONS.—For the
18 purpose of carrying out this section, there are authorized
19 to be appropriated \$20,000,000 for fiscal year 2001, and
20 such sums as may be necessary for fiscal year 2002 and
21 each subsequent fiscal year.”.

1 **SEC. 403. INSTITUTIONAL PROGRAMS FOR PROVIDING EDU-**
2 **CATION ON PROTECTION OF HUMAN SUB-**
3 **JECTS IN RESEARCH.**

4 Section 491 of the Public Health Service Act (42
5 U.S.C. 289), as amended by section 402 of this Act, is
6 amended by adding at the end the following subsection:

7 “(e) INSTITUTIONAL PROGRAMS OF EDUCATION.—
8 For fiscal year 2001 and subsequent fiscal years, the Sec-
9 retary may not make an award of a grant, cooperative
10 agreement, or contract under this Act to a public entity
11 or a private academic institution, or make an award of
12 a grant, cooperative agreement, or contract under this Act
13 for the conduct of research at or through or in affiliation
14 with a public entity or a private academic institution, un-
15 less the public entity or private academic institution (as
16 the case may be) has a comprehensive and ongoing pro-
17 gram to educate investigators and Board members on the
18 protection of human subjects in research.”.

19 **SEC. 404. CERTAIN CLASSIFIED HUMAN-SUBJECT RE-**
20 **SEARCH.**

21 Section 491 of the Public Health Service Act (42
22 U.S.C. 289), as amended by section 403 of this Act, is
23 amended by adding at the end the following subsection:

24 “(f) CERTAIN CLASSIFIED HUMAN-SUBJECT RE-
25 SEARCH.—

1 “(1) IN GENERAL.—Notwithstanding any other
2 provision of law, Federal funds may not be expended
3 for the conduct of classified human-subject research
4 if—

5 “(A) the Institutional Review Board re-
6 viewing the proposal for the research pursuant
7 to this section has under the common rule
8 waived the requirement to obtain the informed
9 consent of the human subjects in the research;
10 or

11 “(B) the research is exempt from the re-
12 quirement under the common rule that the pro-
13 posal for the research be reviewed by such a
14 Board.

15 “(2) DEFINITIONS.—For purposes of this sub-
16 section:

17 “(A) The term ‘classified’, with respect to
18 human-subject research, refers to research that,
19 within the meaning of section 552(b)(1)(A) of
20 title 5, United States Code, is—

21 “(i) specifically authorized under cri-
22 teria established by an Executive order to
23 be kept secret in the interest of national
24 defense or foreign policy; and

1 “(ii) is in fact properly classified pur-
2 suant to such Executive order.

3 “(B) The terms ‘common rule’ and
4 ‘human-subject research’ have the meanings
5 given such terms in section 491A.”.

6 **SEC. 405. RULE OF CONSTRUCTION REGARDING INDI-**
7 **VIDUAL AGENCY OFFICES.**

8 The amendments made by this Act may not be con-
9 strued as terminating any office or other administrative
10 unit in a Federal agency that, on the day before the date
11 of the enactment of this Act, had duties relating to the
12 protection of human subjects in research conducted, sup-
13 ported, or otherwise subject to regulation under Federal
14 law.

15 **SEC. 406. NATIONAL BIOETHICS ADVISORY COMMISSION.**

16 (a) IN GENERAL.—Title XVIII of the Public Health
17 Service Act (42 U.S.C. 300v et seq.) is amended to read
18 as follows:

19 **“TITLE XVIII—NATIONAL BIO-**
20 **ETHICS ADVISORY COMMIS-**
21 **SION**

22 **“SEC. 1801. NATIONAL BIOETHICS ADVISORY COMMISSION.**

23 “(a) ESTABLISHMENT.—There is established the Na-
24 tional Bioethics Advisory Commission (in this title re-
25 ferred to as the ‘Commission’), which shall provide advice

1 and make recommendations to the President, Federal
2 agencies, other appropriate entities, and the public on bio-
3 ethical issues arising from the delivery of health care; re-
4 search on human biology and behavior; and the applica-
5 tions, including the clinical applications, of that research.
6 The Commission is governed by the provisions of the Fed-
7 eral Advisory Committee Act.

8 “(b) FUNCTION.—(1) The National Bioethics Advi-
9 sory Commission shall advise, consult with, and make rec-
10 ommendations to the President, Federal agencies, and
11 other appropriate entities, and also make available to the
12 public the Commission’s advice and recommendations. The
13 Commission’s purview includes the appropriateness of de-
14 partmental, agency, or other governmental programs, poli-
15 cies, assignments, missions, guidelines, and regulations as
16 they relate to bioethical issues arising from the delivery
17 of health care; research on human biology and behavior;
18 and applications, including the clinical applications, of
19 that research. The Commission shall identify broad, over-
20 arching principles to govern the ethical conduct of re-
21 search and the delivery of health care, citing individual
22 projects only as illustrations for such principles. The Com-
23 mission shall not be responsible for the review and ap-
24 proval of individual research projects.

1 “(2) In addition to responding to requests for advice
2 and recommendations from the President, the Commission
3 also may accept suggestions for issues for consideration
4 from the Congress, Federal agencies, and the public. The
5 Commission also may identify other bioethical issues for
6 the purpose of providing advice and recommendations.

7 “(3) The Commission shall consider the following
8 four criteria in establishing priority for its activities:

9 “(A) The public health or public policy urgency
10 of the bioethical issue.

11 “(B) The relation of the bioethical issue to the
12 goals for Federal investment in science and tech-
13 nology.

14 “(C) The absence of another body able to deliber-
15 ate fruitfully on the bioethical issue.

16 “(D) The extent of interest in the issue across
17 the Government.

18 In order to avoid duplication of effort, the Commission
19 is encouraged to review the deliberations of other entities.

20 The Commission may incorporate or otherwise use the re-
21 sults of the deliberations of other entities, as it deems ap-
22 propriate.

23 “(c) STRUCTURE.—(1) The National Bioethics Advi-
24 sory Commission shall consist of not more than 18 mem-
25 bers including the Chairperson. Appointments shall be

1 made by the President, who shall select from knowledge-
2 able non-Government experts and community representa-
3 tives with special qualifications and competence to deal ef-
4 fectively with bioethical issues. At least one member shall
5 be selected from each of the following categories of pri-
6 mary expertise:

7 “(A) Philosophy/theology.

8 “(B) Social/behavioral science.

9 “(C) Law.

10 “(D) Medicine/allied health professions.

11 “(E) Biological research.

12 At least three members shall be selected from the general
13 public, bringing to the Commission expertise other than
14 that listed. The membership shall be approximately evenly
15 balanced between scientists and nonscientists. Close atten-
16 tion will be given to equitable geographic distribution and
17 to ethnic and gender representation.

18 “(2) Members of the Commission will serve for terms
19 of 3 years and no more than 2 consecutive terms and may
20 continue to serve after the expiration of their term until
21 a successor is appointed. A member appointed to fill an
22 unexpired term will be appointed to the remainder of such
23 term. The Chairperson shall be appointed by the Presi-
24 dent. The term of office for the Chairperson shall be two
25 years, renewable by appropriate action of the President.

1 If a vacancy occurs on the Commission, the President shall
2 make an appointment to fulfill the term. Any member ap-
3 pointed to fill a vacancy occurring prior to expiration of
4 the term for which his or her predecessor was appointed
5 shall serve for the remainder of such term. Members may
6 serve after the expiration of their terms until their succes-
7 sors have taken office.

8 “(d) ADMINISTRATIVE PROVISIONS.—(1) The Com-
9 mission may conduct inquiries, hold hearings and establish
10 subcommittees, as necessary. The Commission is author-
11 ized to solicit information from relevant groups.

12 “(2) The Commission may appoint and fix the pay
13 of such staff personnel as it deems desirable. Such per-
14 sonnel shall be appointed subject to the provisions of title
15 5, United States Code, governing appointments in the
16 competitive service, and shall be paid in accordance with
17 the provision of chapter 51 and subchapter III of chapter
18 53 of such title relating to classification and General
19 Schedule pay rates.

20 “(3) The Commission shall appoint an Executive Di-
21 rector, who shall be paid at the level of the Senior Execu-
22 tive Service.

23 “(4) The Commission may procure temporary and
24 intermittent services to the same extent as is authorized
25 by section 3109(b) of title 5 of the United States Code,

1 but at rates for individuals not to exceed the daily equiva-
2 lent of the annual rate of basis pay in effect for grade
3 GS–15 of the General Schedule.

4 “(5) Upon request of the Commission, the head of
5 any Federal agency is authorized to detail, on a reimburs-
6 able basis, any of the personnel of such agency to the
7 Commission to assist it in carrying out its duties under
8 this title.

9 “(6) The Commission is authorized to conduct anal-
10 yses and develop reports or other materials. In order to
11 augment the expertise present on the Commission, the
12 Commission is also authorized to contract for the services
13 of nongovernmental consultants who may conduct anal-
14 yses, prepare reports and background papers, or prepare
15 other materials for consideration by the Commission, as
16 appropriate.

17 “(7) The Commission may secure directly from any
18 Federal agency information necessary to enable it to carry
19 out this title. Upon request of the Chairman of the Com-
20 mission, the head of such agency shall furnish such infor-
21 mation to the Commission.

22 “(8) The Commission shall promptly arrange for such
23 security clearances for its members and appropriate staff
24 as are necessary to obtain access to classified information
25 needed to carry out its duties under this title.

1 “(9) The Commission shall not disclose any informa-
2 tion reported to or otherwise obtained by the Commission
3 which is exempt from disclosure under subsection (a) of
4 section 552 of title 5, United States Code, by reasons of
5 paragraphs (4) and (6) of subsection (b) of such section.

6 “(10) The Administrator of General Services shall
7 provide to the Commission on a reimbursable basis such
8 administrative support services as the Commission may re-
9 quest.

10 “(e) MEETINGS.—Meetings of the Commission shall
11 be held up to 12 times a year at the call of the Chair-
12 person. Meetings of the subcommittee(s) shall be convened
13 as necessary. A Federal Government official shall be
14 present at all meetings. Meetings shall be open to the pub-
15 lic except as determined otherwise by the President. Ad-
16 vance notice of all meetings shall be given to the public.
17 Meetings shall be conducted, and records of proceedings
18 kept, as required by applicable laws and Federal regula-
19 tions.

20 “(f) COMPENSATION.—Members may be com-
21 pensated at a rate not to exceed the maximum pay author-
22 ized by section 3109 of title 5, United States Code, plus
23 per diem and travel expenses as in accordance with stand-
24 ard government travel regulations.

1 “(g) REPORTS.—(1) Reports by the Commission on
2 specific issues shall be submitted to the President, the
3 Congress, appropriate Federal agencies, and other appro-
4 priate entities. Within 60 days of the date a Federal agen-
5 cy receives a recommendation from the Commission that
6 the agency take any action with respect to its rules, poli-
7 cies, guidelines, or regulations, the agency shall publish
8 such recommendation in the Federal Register and shall
9 provide opportunity for interested persons to submit writ-
10 ten data, views, and arguments with respect to adoption
11 of the recommendation. Within the 180-day period begin-
12 ning on the date of such publication, the agency shall de-
13 termine whether the action proposed by such recommenda-
14 tion is appropriate, and to the extent that it determines
15 that—

16 “(A) such action is not appropriate, the agency
17 shall, within such time period, provide the Commis-
18 sion with, and publish in the Federal Register, a no-
19 tice of such determination (including an adequate
20 statement of the reasons for the determination); or

21 “(B) such action is appropriate, the agency
22 shall undertake such action as expeditiously as fea-
23 sible and shall notify the Commission of the deter-
24 mination and the action undertaken.

1 Executive summaries of each report of the Commission
2 shall be published in the Federal Register or on the World
3 Wide Web. Such summaries shall specifically list the agen-
4 cy to which any recommendations are directed and the
5 date by which such responses are required.

6 “(2) An annual report shall be submitted to the
7 President, the Congress, and appropriate Federal agen-
8 cies. It shall contain, at a minimum—

9 “(A) the Commission’s function;

10 “(B) a list of members and their business ad-
11 dresses;

12 “(C) the dates and places of meetings;

13 “(D) a summary of the Commission’s activities
14 during the year;

15 “(E) a summary of the Commission’s rec-
16 ommendations made during the year; and

17 “(F) a summary of responses made by Federal
18 agencies to the Commission’s recommendations dur-
19 ing the year.

20 “(h) AUTHORIZATION OF APPROPRIATIONS.—For the
21 purposes of carrying out this section, there are authorized
22 to be appropriated \$5,000,000 for fiscal year 2001, and
23 such sums as may be necessary for fiscal year 2002 and
24 each subsequent fiscal year.”.

1 (b) STUDY ON RESEARCH INVOLVING CHILDREN.—

2 The National Bioethics Advisory Commission under sec-
3 tion 1801 of the Public Health Service Act shall conduct
4 a thorough review and report on the research involving—

5 (1) the process of obtaining informed consent
6 from parents and children, including (A) the defini-
7 tions of ‘informed consent’ and ‘assent’, and (B)
8 substitute decisionmaking, including who can serve
9 as a legally authorized representative (as defined in
10 subpart A of part 46 of title 45, Code of Federal
11 Regulations);

12 (2) the requirements for what elements of infor-
13 mation should be disclosed to parents and children
14 (such as risks and benefits of, and alternatives to
15 participation in, the research project, and data of
16 prior adverse events);

17 (3) determining comprehension by parents and
18 children of the informed consent document, includ-
19 ing the distinction between research and therapeutic
20 treatment;

21 (4) the requirements of what additional meas-
22 ures should be undertaken with respect to protecting
23 children from undue risk;

1 (5) the appropriateness of the regulations for
2 children of different ages, from infants to adoles-
3 cents and emancipated minors;

4 (6) payment (financial and other) for research
5 participation; and

6 (7) the unique roles and responsibilities of
7 IRBs in reviewing research involving children, in-
8 cluding membership composition.

○