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 Representatives of the United States of America in Congress assembled,

2 SECTION 1. SHORT TITLE.

3 This Act may be cited as the “Human Research Subject Protections Act of 2000”.

4 SEC. 2. FINDINGS AND PURPOSES.

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

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

(2) 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, subpart A of these regulations was adopted by 16 additional Federal agencies to apply to any research which these agencies may conduct or sponsor.

(3) Between 1974 and 1983, Congress enacted two Public Laws that established ethical advisory bodies. Public Law 91–348 established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral 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).
(4) 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.

(5) 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.

(6) In 1996, Congress enacted the Health Insurance Portability and Accountability Act, which established an August 21, 1999, deadline to enact comprehensive health privacy rules. Failure to meet that deadline triggered a requirement for the Secretary of Health and Human Services to issue final health privacy regulations by February 2000.
(7) In 1998 and 2000, the Department of Health and Human Services’s Inspector General found that the effectiveness of Institutional Review Board was “in jeopardy” and attention needed to be directed to enhancing human subject protections for a widening scope of clinical investigation.

(8) In 1998 and 1999, the National Bioethics Advisory Commission found that Federal protections do not always contain specific protections for certain vulnerable populations and that existing regulations do not adequately address issues involving human biological materials.

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

(10) 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, device, or biologic 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.
(11) Research institutions that receive Federal funds for conducting research involving human subjects are not required to apply the protections of part 46 of title 45, Code of Federal Regulations, to all research conducted at the institution. Many, but not all, research institutions have voluntarily made this commitment.

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

(13) 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 and vulnerable-populations protections to all human research subjects independent of setting and funding source;
(2) to prohibit the provision of Federal support for classified research that is not approved by an institutional review board and require disclosure to human research subjects of certain information regarding classified research; and

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

**TITLE I—HUMAN SUBJECT PROTECTIONS**

**SEC. 101. PROTECTION OF HUMAN SUBJECTS IN RESEARCH; UNIFORM NATIONAL APPLICABILITY OF COMMON RULE AND PROVISIONS PROTECTING VULNERABLE POPULATIONS.**

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:

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“SEC. 491A. (a) IN GENERAL.—All human-subject research shall be conducted in accordance with the provisions of subpart A of part 46 of title 45, Code of Federal Regulations (referred to in this section as the ‘common rule’), and as applicable to the human subjects used in
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such research, with the provisions of subparts B through D of such part 46 (referred to in this section as ‘vulnerable-populations rules’), except to the extent that such provisions are in conflict with this section.

“(b) DEFINITIONS.—

“(1) HUMAN-SUBJECT RESEARCH.—For purposes of this section, the term ‘human-subject research’ means research that is conducted with one or more human subjects and—

“(A) is conducted, supported, or otherwise subject to regulation under a provision of Federal law (other than this section), without regard to whether the Federal agency that administers such law has taken administrative action to make the common rule applicable to the agency; or

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

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

“(A) The term ‘common rule’ has the meaning indicated for such term in subsection (a).
“(B) The term ‘Federal agency’ has the meaning given the term ‘Executive agency’ in section 105 of title 5, United States Code.

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

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

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

SEC. 102. SCOPE OF AUTHORITY OF SECRETARY.

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

“(c) Scope of Authority of Secretary.——

“(1) In general.—The common rule (including the exemptions described in section 46.101(b) of title 45, Code of Federal Regulations) and the vulnerable-populations rules, as in effect on the day before the date of the enactment of the Human Research Subject Protections Act of 2000, continue to be in effect on and after such date, subject to paragraph (2).
“(2) Modifications.—

“(A) In general.—This section may not be construed as affecting the authority of the Secretary to modify the provisions of the common rule 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.

“(B) Agency-specific additional protections.—With respect to human-subject research that is conducted, supported, or otherwise subject to regulation under a provision of Federal law (other than this section), the Secretary may under subparagraph (A) permit the Federal agency involved to establish additional protections for the protection of human subjects if the Secretary determines that such additional protections are not in conflict with protections established under this section.

“(3) Suspension and revocation.—After providing notice and an opportunity for a hearing, the Secretary may suspend or revoke the registration, impose restrictions during a corrective action period, or withhold Federal funding to an Institu-
tional Review Board described under subsection (e)(1)(F).

SEC. 103. ENHANCED HUMAN SUBJECT PROTECTIONS FOR PEOPLE WITH DIMINISHED DECISIONMAKING CAPACITY.

Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall, for purposes of section 491A of the Public Health Service Act, promulgate regulations to enhance the protection of people with diminished decisionmaking capacity with respect to their participation as subjects in clinical research.

TITLE II—INFORMED CONSENT

SEC. 201. RIGHT OF INFORMED CONSENT.

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

“(d) Right of Informed Consent.—

“(1) In general.—Except as provided by the Secretary by regulation, no investigator may involve a living human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative.
“(2) Disclosure and Understanding.—

During the informed consent process, all human subjects shall be given full and complete information relevant to the proposed research in language and in a manner that allows them to understand the information and make an informed decision, free of coercion, regarding their participation in research. An individual knowledgeable about the proposed research must provide this information such that any questions the potential subject has can be answered.

“(3) Consent Form.—A human subject of research shall be given a consent form that includes, at a minimum, the basic elements of informed consent, including the purpose of the study, the potential risks, benefits and alternatives to participation, the distinction between research and therapeutic treatment, the right to withdraw participation at any time, investigator financial interest under paragraph (4)(B), and the sponsor of the study. A copy of the signed consent form shall be given to the human subject and contact information for the Office for Protection of Research Subjects for questions or to report concerns.”.
SEC. 202. WRITTEN ATTESTATION AND DISCLOSURE.

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

“(4) WRITTEN ATTESTATION AND DISCLOSURE.—

“(A) IN GENERAL.—An investigator engaged in research involving human subjects shall file a written attestation of familiarity with and agreement to comply with the requirements of human subject research protections, including informed consent.

“(B) FINANCIAL INTEREST.—An investigator engaged in research involved in human subjects shall disclose to the subjects investigator financial interest in the research, including capitation payments, disclosure of sponsors of the research and any conflict deemed necessary by the Institutional Review Board.”.

TITLE III—INSTITUTIONAL REVIEW BOARDS

SEC. 301. REQUIREMENTS FOR BOARD.

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

“(e) INSTITUTIONAL REVIEW BOARDS.—
“(1) Requirements for boards.—Human-subject research may not be conducted unless an Institutional Review Board established pursuant to this section has, for purposes of the common rule (and the vulnerable-populations rules, as applicable), approved the proposal for such research. The approval by the Board of the proposal for the research is not effective unless, in addition to conditions established by the Secretary, the following conditions are met:

“(A) Of the membership of such Board:

“(i) Not fewer than 2 members or 20 percent of all members (whichever is greater) are individuals whose primary expertise is in scientific areas.

“(ii) Not fewer than 2 members or 20 percent of all members (whichever is greater) are individuals whose primary expertise is in nonScientific areas.

“(iii) Not fewer than 2 members or 20 percent of all members (whichever is greater) are individuals who are not affiliated with the institution with respect to which the Board is established (other than by serving on the Board), who are not im-
mediate family members of any individual who is affiliated with the institution, and who do not have a conflict of interest (including nonproprietary interest).

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

“(C) With respect to the review by the Board of a proposal for human-subject research, the Board does not consider a quorum to have been established for a meeting unless the members present at the meeting include one or more members who are individuals described in clauses (i) and (ii) of subparagraph (A) and one or more members who are individuals described in clause (iii) of such subparagraph.

“(D) The institution with respect to which the Board is employed by ensures that the Board has an orientation and continuing education program for new members of the Board,
and with respect to ethical matters that relate to research, a continuing education program for all members of the Board.

“(E) The institution with respect to which the Board is employed by is in compliance with such conditions as the Secretary may by regulation establish for purposes of ensuring that the institution is providing to the Board and recovering resources from the research sponsor sufficient to carry out the responsibilities of the Board pursuant to this section.

“(F) The Board has submitted to the Secretary a registration informing the Secretary of the existence of the Board, and the registration was is in such form, was made in such manner, and contained such agreements, assurances, and information as the Secretary requested regarding functions of the Board under this section.

“(G) The Board has submitted to the Secretary such reports regarding the Board as the Secretary has requested.”.
SEC. 302. NOTIFICATION OF INSTITUTIONAL REVIEW BOARD.

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

“(2) NOTIFICATION OF INSTITUTIONAL REVIEW BOARD.—In submitting to an Institutional Review Board a proposal for human-subject research, the sponsors and investigators for the research shall notify the Board—

“(A) whether the proposal has been submitted to any other Institutional Review Board;

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

“(C) whether the sponsors, investigators, or institutions have been disqualified or restricted by any Federal entity in their ability to participate in human subject research, or are ineligible to receive investigational new drugs, or have agreed to some restriction.”.

SEC. 303. ACTIVITIES.

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

“(3) ACTIVITIES.—
“(A) **DATA COLLECTION.**—An Institutional Review Board shall compile annual data on the number of new research proposals reviewed, the number of continuing research projects reviewed, the number of human subjects involved in approved research, and other information to be determined by the Secretary, and report such data to the Office for Protection of Research Subjects.

“(B) **IMPROVED MONITORING.**—The Secretary shall promulgate regulations regarding data safety and monitoring boards and clinical trial monitoring plans. Such regulations shall specify minimum reporting requirements to Institutional Review Boards and the Office for Protection of Research Subjects.

“(C) **MULTIPLE SITE RESEARCH.**—The Secretary shall promulgate regulations regarding the conduct of research at multiple research sites, including international sites. Such regulations shall specify minimum reporting requirements to Institutional Review Boards and the Office for Protection of Research Subjects, conditions requiring the establishment of data safety and monitoring boards, and other require-
ments necessary to assure compliance with this section.”.

SEC. 304. DISCLOSURE OF INTERESTS.

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

“(4)(A) All researchers shall disclose to an Institutional Review Board any actual, perceived, or potential conflicts of interest. All researchers shall disclose to potential subjects financial interests they have in research for which the subjects are being recruited, including capitation payments, disclosure of sponsors of the research and any conflict deemed necessary by the Institutional Review Board.

“(B) All Board members shall disclose any actual, perceived, or potential conflicts of interest to the Board, including but not limited to—

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

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

“(iii) financial relationships or arrangements with private sponsors of research projects being reviewed by the Board and provide that
information to the Office for Protection of Research Subjects.

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

SEC. 305. ACCREDITATION.

(a) In general.—Section 491A(e)(1) of the Public Health Service Act, as added by section 301 of this Act, is amended by adding at the end the following subparagraph:

“(H)(i) Effective two years after the date of the enactment of the Human Research Subject Protections Act of 2000, the Board has been accredited by a nonprofit private entity approved by the Secretary for purposes of this subparagraph.”.

(b) Requirements of accrediting body.—Section 491A(e)(1)(H) of the Public Health Service Act, as added by subsection (a) of this section, is amended by adding at the end the following clauses:

“(ii) The accrediting body must meet standards for accreditation established by the Secretary.
“(iii) The accrediting body shall provide satisfactory assurances that it will comply with such standards.

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

“(v) The Secretary may withdraw approval of the accrediting body if the Secretary determines that the accrediting body does not meet the standards under clause (ii).”.

SEC. 306. COST RECOVERY.

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

“(5) COST RECOVERY.—Institutions may recover costs associated with compliance for human subject protections under this Act from government sponsors of research as direct costs.”.

SEC. 307. APPLICABILITY OF REQUIREMENTS.

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

“(f) APPLICABILITY OF REQUIREMENTS.—The requirements of this section apply on and after the date of the enactment of the Human Research Subject Protections Act of 2000.”.
TITLE IV—FEDERAL OVERSIGHT

SEC. 401. ESTABLISHMENT OF OFFICE FOR PROTECTION OF RESEARCH SUBJECTS.

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

(1) by redesignating subsection (b) as subsection (c);

(2) by striking “Sec. 491. (a) The Secretary shall by regulation require” and inserting the following:

“(b) REQUIREMENT REGARDING INSTITUTIONAL REVIEW BOARDS.—The Secretary shall by regulation require”; and

(3) by inserting before subsection (b) (as redesignated by paragraph (2) of this subsection) the following:

“Sec. 491. (a) OFFICE FOR PROTECTION OF RESEARCH SUBJECTS.—There is established within the Office of the Secretary an office to be known as the Office for Protection of Research Subjects (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) CONFORMING AMENDMENTS.—Section 491 of the
Public Health Service Act (42 U.S.C. 289) is amended
in subsection (c) (as redesignated by subsection (a)(1) of
this section)—

(1) by striking “(c)(1) The Secretary shall” and
inserting the following:
“(c) ETHICS GUIDANCE PROGRAM.—
“(1) IN GENERAL.—The Secretary shall”; and
(2) by striking “(2) The Secretary shall” and
inserting the following:
“(2) PROCESS REGARDING VIOLATIONS.—The
Secretary shall”.

SEC. 402. AUTHORIZATION OF APPROPRIATIONS.

Section 491 of the Public Health Service Act (42
U.S.C. 289), as amended by section 401 of this Act, is
amended by adding at the end the following subsection:
“(d) AUTHORIZATION OF APPROPRIATIONS.—For the
purpose of carrying out this section, there are authorized
to be appropriated $20,000,000 for fiscal year 2001, and
such sums as may be necessary for fiscal year 2002 and
each subsequent fiscal year.”.
SEC. 403. INSTITUTIONAL PROGRAMS FOR PROVIDING EDUCATION ON PROTECTION OF HUMAN SUBJECTS IN RESEARCH.

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

“(e) INSTITUTIONAL PROGRAMS OF EDUCATION.—

For fiscal year 2001 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) has a comprehensive and ongoing program to educate investigators and Board members on the protection of human subjects in research.”.

SEC. 404. CERTAIN CLASSIFIED HUMAN-SUBJECT RESEARCH.

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

“(f) CERTAIN CLASSIFIED HUMAN-SUBJECT RESEARCH.—
“(1) IN GENERAL.—Notwithstanding any other provision of law, Federal funds may not be expended for the conduct of classified human-subject research if—

“(A) the Institutional Review Board reviewing the proposal for the research pursuant to this section has under the common rule waived the requirement to obtain the informed consent of the human subjects in the research; or

“(B) the research is exempt from the requirement under the common rule that the proposal for the research be reviewed by such a Board.

“(2) DEFINITIONS.—For purposes of this subsection:

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

“(i) specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy; and
“(ii) is in fact properly classified pursuant to such Executive order.

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

SEC. 405. RULE OF CONSTRUCTION REGARDING INDIVIDUAL AGENCY OFFICES.

The amendments made by this Act may not be construed as terminating any office or other administrative unit in a Federal agency that, on the day before the date of the enactment of this Act, had duties relating to the protection of human subjects in research conducted, supported, or otherwise subject to regulation under Federal law.

SEC. 406. NATIONAL BIOETHICS ADVISORY COMMISSION.

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

“TITLE XVIII—NATIONAL BIOETHICS ADVISORY COMMISSION

“SEC. 1801. NATIONAL BIOETHICS ADVISORY COMMISSION.

“(a) ESTABLISHMENT.—There is established the National Bioethics Advisory Commission (in this title referred to as the ‘Commission’), which shall provide advice
and make recommendations to the President, Federal
agencies, other appropriate entities, and the public on bio-
ethical issues arising from the delivery of health care; re-
search on human biology and behavior; and the applica-
tions, including the clinical applications, of that research.
The Commission is governed by the provisions of the Fed-
eral Advisory Committee Act.

“(b) Function.—(1) The National Bioethics Advi-
sory Commission shall advise, consult with, and make rec-
ommendations to the President, Federal agencies, and
other appropriate entities, and also make available to the
public the Commission’s advice and recommendations. The
Commission’s purview includes the appropriateness of de-
partmental, agency, or other governmental programs, poli-
cies, assignments, missions, guidelines, and regulations as
they relate to bioethical issues arising from the delivery
of health care; research on human biology and behavior;
and applications, including the clinical applications, of
that research. The Commission shall identify broad, over-
arching principles to govern the ethical conduct of re-
search and the delivery of health care, citing individual
projects only as illustrations for such principles. The Com-
mission shall not be responsible for the review and ap-
proval of individual research projects.
“(2) In addition to responding to requests for advice and recommendations from the President, the Commission also may accept suggestions for issues for consideration from the Congress, Federal agencies, and the public. The Commission also may identify other bioethical issues for the purpose of providing advice and recommendations.

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

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

“(B) The relation of the bioethical issue to the goals for Federal investment in science and technology.

“(C) The absence of another body able to deliberate fruitfully on the bioethical issue.

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

In order to avoid duplication of effort, the Commission is encouraged to review the deliberations of other entities. The Commission may incorporate or otherwise use the results of the deliberations of other entities, as it deems appropriate.

“(e) STRUCTURE.—(1) The National Bioethics Advisory Commission shall consist of not more than 18 members including the Chairperson. Appointments shall be
made by the President, who shall select from knowledgeable non-Government experts and community representatives with special qualifications and competence to deal effectively with bioethical issues. At least one member shall be selected from each of the following categories of primary expertise:

“(A) Philosophy/theology.

“(B) Social/behavioral science.

“(C) Law.

“(D) Medicine/allied health professions.

“(E) Biological research.

At least three members shall be selected from the general public, bringing to the Commission expertise other than that listed. The membership shall be approximately evenly balanced between scientists and nonscientists. Close attention will be given to equitable geographic distribution and to ethnic and gender representation.

“(2) Members of the Commission will serve for terms of 3 years and no more than 2 consecutive terms and may continue to serve after the expiration of their term until a successor is appointed. A member appointed to fill an unexpired term will be appointed to the remainder of such term. The Chairperson shall be appointed by the President. The term of office for the Chairperson shall be two years, renewable by appropriate action of the President.
If a vacancy occurs on the Commission, the President shall make an appointment to fulfill the term. Any member appointed to fill a vacancy occurring prior to expiration of the term for which his or her predecessor was appointed shall serve for the remainder of such term. Members may serve after the expiration of their terms until their successors have taken office.

“(d) Administrative Provisions.—(1) The Commission may conduct inquiries, hold hearings and establish subcommittees, as necessary. The Commission is authorized to solicit information from relevant groups.

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

“(3) The Commission shall appoint an Executive Director, who shall be paid at the level of the Senior Executive Service.

“(4) The Commission may procure temporary and intermittent services to the same extent as is authorized by section 3109(b) of title 5 of the United States Code,
but at rates for individuals not to exceed the daily equivalent of the annual rate of basis pay in effect for grade GS–15 of the General Schedule.

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

“(6) The Commission is authorized to conduct analyses and develop reports or other materials. In order to augment the expertise present on the Commission, the Commission is also authorized to contract for the services of nongovernmental consultants who may conduct analyses, prepare reports and background papers, or prepare other materials for consideration by the Commission, as appropriate.

“(7) The Commission may secure directly from any Federal agency information necessary to enable it to carry out this title. Upon request of the Chairman of the Commission, the head of such agency shall furnish such information to the Commission.

“(8) The Commission shall promptly arrange for such security clearances for its members and appropriate staff as are necessary to obtain access to classified information needed to carry out its duties under this title.
“(9) The Commission shall not disclose any information reported to or otherwise obtained by the Commission which is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, by reasons of paragraphs (4) and (6) of subsection (b) of such section.

“(10) The Administrator of General Services shall provide to the Commission on a reimbursable basis such administrative support services as the Commission may request.

“(e) MEETINGS.—Meetings of the Commission shall be held up to 12 times a year at the call of the Chairperson. Meetings of the subcommittee(s) shall be convened as necessary. A Federal Government official shall be present at all meetings. Meetings shall be open to the public except as determined otherwise by the President. Advance notice of all meetings shall be given to the public. Meetings shall be conducted, and records of proceedings kept, as required by applicable laws and Federal regulations.

“(f) COMPENSATION.—Members may be compensated at a rate not to exceed the maximum pay authorized by section 3109 of title 5, United States Code, plus per diem and travel expenses as in accordance with standard government travel regulations.
“(g) REPORTS.—(1) Reports by the Commission on specific issues shall be submitted to the President, the Congress, appropriate Federal agencies, and other appropriate entities. Within 60 days of the date a Federal agency receives a recommendation from the Commission that the agency take any action with respect to its rules, policies, guidelines, or regulations, the agency shall publish such recommendation in the Federal Register and shall provide opportunity for interested persons to submit written data, views, and arguments with respect to adoption of the recommendation. Within the 180-day period beginning on the date of such publication, the agency shall determine whether the action proposed by such recommendation is appropriate, and to the extent that it determines that—

“(A) such action is not appropriate, the agency shall, within such time period, provide the Commission with, and publish in the Federal Register, a notice of such determination (including an adequate statement of the reasons for the determination); or

“(B) such action is appropriate, the agency shall undertake such action as expeditiously as feasible and shall notify the Commission of the determination and the action undertaken.
Executive summaries of each report of the Commission shall be published in the Federal Register or on the World Wide Web. Such summaries shall specifically list the agency to which any recommendations are directed and the date by which such responses are required.

“(2) An annual report shall be submitted to the President, the Congress, and appropriate Federal agencies. It shall contain, at a minimum—

“(A) the Commission’s function;
“(B) a list of members and their business addresses;
“(C) the dates and places of meetings;
“(D) a summary of the Commission’s activities during the year;
“(E) a summary of the Commission’s recommendations made during the year; and
“(F) a summary of responses made by Federal agencies to the Commission’s recommendations during the year.

“(h) AUTHORIZATION OF APPROPRIATIONS.—For the purposes of carrying out this section, there are authorized to be appropriated $5,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal year 2002 and each subsequent fiscal year.”.
(b) Study on Research Involving Children.—

The National Bioethics Advisory Commission under section 1801 of the Public Health Service Act shall conduct a thorough review and report on the research involving—

(1) the process of obtaining informed consent from parents and children, including (A) the definitions of ‘informed consent’ and ‘assent’, and (B) substitute decisionmaking, including who can serve as a legally authorized representative (as defined in subpart A of part 46 of title 45, Code of Federal Regulations);

(2) the requirements for what elements of information should be disclosed to parents and children (such as risks and benefits of, and alternatives to participation in, the research project, and data of prior adverse events);

(3) determining comprehension by parents and children of the informed consent document, including the distinction between research and therapeutic treatment;

(4) the requirements of what additional measures should be undertaken with respect to protecting children from undue risk;
(5) the appropriateness of the regulations for children of different ages, from infants to adolescents and emancipated minors;

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

(7) the unique roles and responsibilities of IRBs in reviewing research involving children, including membership composition.