Appendix B

Legislation, Regulations, or Statutes for Previous U.S. Bioethics Initiatives

NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

Reprinted below is Public Law 93-348, which established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The National Commission operated from 1974-78.

Title H-Protection of Human Subjects of Biomedical and Behavioral Research

Part A—National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Establishment of Commission

Section **201. (a) There is** established a Commission to be known as the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (hereinafter in this title referred to as the "Commission").

(b)(1) The Commission shall be composed of eleven members appointed by the Secretary of Health, Education, and Welfare (hereinafter in this title referred to as the 'Secretary' '). The Secretary shall select members of the Commission from individuals distinguished in the fields of medicine, law, ethics, theology, the biological, physical, behavioral and social sciences, philosophy, humanities, health administration, government, and public affairs; but five (and not more than five) of the members of the Commission shall be individuals who are or who have been engaged in biomedical or behavioral research involving human subjects. In appointing members of the Commission, the Secretary shall give consideration to recommendations from the National Academy of Sciences and other appropriate entities. Members of the Commission shall be appointed for the life of the Commission. The Secretary shall appoint the members of the Commission within sixty days of the date of the enactment of this Act.

(2)(A) Except as provided in subparagraph (B), members of the Commission shall each be entitled to receive the daily equivalent of the annual rate of the basic pay in effect for grade GS-18 if the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of the duties of the Commission.

(B) Members of the Commission who are fall-time officers or employees of the United States shall receive no additional pay on account of their service on the Commission.

(C) While away from their homes or regular places of business in the performance of duties of the Commission, members of the Commission shall be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in the Government service are allowed expenses under section 5703@) of Title 5 of the United States Code.

(c) The chairman of the Commission shall be selected by the members of the Commission from among their number.

(d)(1) 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 provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

(2) 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 basic pay in effect for grade GS-18 of the General Schedule.

Commission Duties

Sec. 202. (a) The Commission shall carry out the following:

(l)(A) The Commission shall (i) conduct a comprehensive investigation and study to identify the basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human subjects, (ii) develop guidelines which should be followed in such research to assure that it is conducted in accordance with such principles, and (iii) make recommendations to the Secretary (I) for such administrative action as may be appropriate to apply such guidelines to biomedical and behavioral research conducted or supported under programs administered by the Secretary, and (II) concerning any other matter pertaining to the protection of human subjects of biomedical and behavioral research.

(B) In carrying out subparagraphs (A), the Commission shall consider at least the following:

(i) The boundaries between biomedical or behavioral research involving human subjects and the accepted and routine practice of medicine.

(ii) The role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects.

(iii) Appropriate guidelines for the selection of human subjects for participation in biomedical and behavioral research.

(iv) The nature and definition of informed consent in various research settings.

(v) Mechanisms for evaluating and monitoring the performance of Institutional Review Boards established in accordance with section 474 of the Public Health Service Act and appropriate enforcement mechanisms for carrying out their decisions.

(C) The Commission shall consider the appropriateness of applying the principles and guidelines identified and developed under subparagraph (A) to the delivery of health services to patients under programs conducted or supported by the Secretary.

(2) The Commission shall identify the requirements for informed consent to participation in biomedical and behavioral research by children, prisoners, and the institutionalized mentally infirm. The Commission shall investigate and study biomedical and behavioral research conducted or supported under programs administered by the Secretary and involving children, prisoners, and the institutionalized mentally infirm to determine the nature of the consent obtained from such persons or their legal representatives before such persons were involved in such research; the adequacy of the information given them respecting the nature and purpose of the research, procedures to be used, risks and discomforts, anticipated benefits from the research, and other matters necessary for informed consent; and the competence and the freedom of the persons to make a choice for or against involvement in such research. On the basis of such investigation and study the Commission shall make such recommendations to the Secretary as it determines appropriate to assure that biomedical and behavioral research conducted or supported under programs administered by him meets the requirements respecting informed consent identified by the Commission. For purposes of this paragraph, the term ‘‘children” means individuals who have not attained the

legal age of consent to participate in research as determined under the applicable law of the jurisdiction in which the research is to be conducted; the term "prisoner" means individuals involuntarily confined in correctional institutions or facilities (as defined in section 601 of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3781)); and the term "institutionalized mentally infirm" includes individuals who are mentally ill, mentally retarded, emotionally disturbed, psychotic, or senile, or who have other impairments of a similar nature and who reside as patients in an institution.

(3) The Commission shall conduct an investigation and study to determine the needf or a mechanism to assure that human subjects in biomedical and behavioral research not subject to regulation by the Secretary are protected. If the Commission determines that such a mechanism is needed, it shall develop and recommend to the Congress such a mechanism. The Commission may contract for the design of such a mechanism to be included in such recommendations.

(b) The Commission shall conduct an investigation and study of the nature and extent of research involving living fetuses, the purposes for which such research has been undertaken, and alternative means for achieving such purposes. The Commission shall, not later than the expiration of the 4-month period beginning on the first day of the first month that follows the date on which all the members of the Commission have taken office, recommend to the Secretary policies defining the circumstances (if any) under which such research may be conducted or supported.

(c) The Commission shall conduct an investigation and study of the use of psychosurgery in the United States during the five-year period ending December 31, 1972. The Commission shall determine the appropriateness of its use, evaluate the need for it, and recommend to the Secretary policies defining the circumstances (if any) under which its use may be appropriate. For purposes of this paragraph, the term 'psychosurgery' means brain surgery on (1) normal brain tissue of an individual, who does not suffer from any physical disease, for the purpose of changing or controlling the behavior or emotions of such individual, or (2) diseased brain tissue of an individual, if the sole object of the performance of such surgery is to control, change, or affect any behavioral or emotional disturbance of such individual. Such term does not include brain surgery designed to cure or ameliorate the effects of epilepsy and electric shock treatments.

(d) The Commission shall make recommendations to the Congress respecting the functions and authority of the National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research to be established under section 217(f) of the Public Health Service Act.

Special Study

Section 203. The Commission shall undertake a comprehensive study of the ethical, social, and legal implications of advances in biomedical and behavioral research and technology. Such study shall include-

(1) an analysis and evaluation of scientific and technological advances in past, present, and projected biomedical and behavioral research and services;

(2) an analysis and evaluation of the implementations of such advances, both for individuals and for society;

(3) an analysis and evaluation of laws and moral and ethical principles governing the use of technology in medical practice;

(4) an analysis and evaluation of public understanding of and attitudes toward such implications and laws and principles; and

(5) an analysis and evaluation of implications for public policy of such findings as are made by the Commission with respect to advances in biomedical and behavioral research and technology and public attitudes toward such advances.

Administrative Provisions

Section 204. (a) The Commission may for the purpose of carrying out its duties under sections 202 and 203 hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Commission deems advisable.

(b) The Commission may secure directly from any department or agency of the United States information necessary to enable it to carry out its duties. Upon the request of the chairman of the Commission, the head of such department or agency shall furnish such information to the Commission.

(c) The Commission shall not disclose any information reported to or otherwise obtained by it in carrying out its duties which (1) identifies any individual who has been the subject of an activity studied and investigated by the Commission, or (2) which concerns any information which contains or relates to a trade secret or other matter referred to in section 1905 of Title 18 of the United States Code.

(d) Except as provided in subsection (b) of section 202, the Commission shall complete its duties under sections 202 and 203 not later than the expiration of the 24-month period beginning on the first day of the first month that follows the date on which all the members of the Commission have taken office. The Commission shall make periodic reports to the President, the Congress, and the Secretary respecting its activities under sections 202 and 203 and shall, not later than ninety days after the expiration of such 24-month period, make a final report to the President, the Congress, and the Secretary respecting such activities and including its recommendations for administrative action and legislation.

(e) The Commission shall cease to exist thirty days following the submission of its final report pursuant to subsection (d).

Duties of the Secretary

Section 205. Within 60 days of the receipt of any recommendation made by the Commission under section 202, the Secretary shall publish it in the Federal Register and provide opportunity for interested persons to submit written data, views, and arguments with respect to such recommendation. The Secretary shall consider the Commission's recommendation and relevant matter submitted with respect to it and, within 180 days of the date of its publication in the Federal Register, the Secretary shall (1) determine whether the administrative action proposed by such recommendation is appropriate to assure the protection of human subjects of biomedical and behavioral research conducted or supported under programs administered by him, and (2) if he determines that such action is not so appropriate, publish in the Federal Register such determination together with an adequate statement of the reasons for his determination. If the Secretary determines that administrative action recommended by the Commission should be undertaken by him, he shall undertake such action as expeditiously as is feasible.

Part B—Miscellaneous

National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research

Section 211. (a) Section 217 of the Public Health Service Act is amended by adding at the end of the following new subsection:

"(f)(l) There shall be established a National Advisory ***council*** for the **Protection** of Subjects of Biomedical and Behavioral Research (hereinafter in this subsection referred to as the "Council") which shall consist of the Secretary who shall be Chairman and not less than seven nor more than fifteen other members who shall be appointed by the Secretary without regard to the provisions of Title 5, United States Code, governing appointments in the competitive service. The Secretary shall select members of the Council from individuals distinguished in the fields of medicine, law, ethics, theology, the biological, physical, behavioral and social sciences, philosophy, humanities, health administration, government, and public affairs; but three (and not more than three) of the members of the Council shall be individuals who are or who have been engaged in biomedical or behavioral research involving human subjects. No individual who was appointed to be a member of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (established under Title II of the National Research Act) may be appointed to be a member of the Council. The appointed members of the Council shall have terms of office of four years, except that for the purposes of staggering the expiration of the terms of office of the Council members, the Secretary shall, at the time of appointment, designate a term of office of less than four years for members first appointed to the Council.

"(2) The Council shall—

"(A) advise, consult with, and make recommendations to, the Secretary concerning all matters pertaining to the protection of human subjects of biomedical and behavioral research;

"(B) review policies, regulations, and other requirements of the Secretary governing such research to determine the extent to which such policies, regulations, and requirements require and are effective in requiring observance in such research of the basic ethical principles which should underlie the conduct of such research and, to the extent such policies, regulations, or requirements do not require or are not effective in requiring observance of such principles, make recommendations to the Secretary respecting appropriate revision of such policies, regulations, or requirements; and

"(C) review periodically changes in the scope, purpose, and types of biomedical and behavioral research being conducted and the impact such changes have on the policies, regulations, and other requirements of the Secretary for the protection of human subjects of such research.

"(3) The Council may disseminate to the public such information, recommendations, and other matters relating to its functions as it deems appropriate.

"(4) Section 14 of the Federal Advisory Committee Act shall not apply with respect to the Council."

(b) The amendment made by subsection (a) shall take effect July 1,1976,

Institutional Review Boards; Ethics Guidance Program

Section 212. (a) Part I of Title IV of the Public Health Service Act, as amended by section 103 of this Act, is amended by adding at the end the following new section:

"Institutional Review Boards; Ethics Guidance Program

"Section 474. (a) The Secretary shall by regulation require that each entity which applies for a grant or contract under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grantor contract assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an 'Institutional Review Board') to review biomedical and behavioral research involving human subjects conducted at or sponsored by such entity in order to protect the rights of the human subjects of such research.

"(b) The Secretary shall establish a program within the Department under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately. "

(b) The Secretary of Health, Education, and Welfare shall within 240 days of the date of the enactment of this Act promulgate such regulations as maybe required to carry out section 474(a) of the Public Health Service Act. Such regulations shall apply with respect to applications for grants and contracts under such Act submitted after promulgation of such regulations.

Limitation on Research

Section 213. Until the Commission has made its recommendations to the Secretary pursuant to section 202(b), the Secretary may not conduct or support research in the United States or abroad on a living human fetus, before or after the inducted abortion of such fetus unless such research is done for the purpose of assuring the survival of such fetus.

Individual Rights

Section 214. (a) Subsection (c) of section 401 of the Health Programs Extension Act of 1973 is amended (1) by inserting "(l)" after "(c)", (2) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively, and (3) by adding at the end the following new paragraph:

''(2) No entity which receives after the date of enactment of this paragraph a grant or contract for biomedical or behavioral research under any program administered by the Secretary of Health, Education, and Welfare may—

"(A) discriminate in the employment, promotion, or termination of employment of any physician or other health care personnel, or

"(B) discriminate in the extension of staff or other privileges to any physician or other health care personnel, because he performed or assisted in the performance of any lawful health service or research activity, because he refused to perform or assist in the performance of any such service or activity on the grounds that his performance or assistance in the performance of such service or activity would be contrary to his religious beliefs or moral convictions, or because of his religious beliefs or moral convictions respecting any such service or activity."

(b) Section 401 of such Act is amended by adding at the end the following new subsection:

"(d) No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health, Education, and Welfare if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions. "

Special Project Grants and Contracts

Section 215. Section 772(a)(7) of the Public Health Service Act is amended by inserting immediately before the semicolon at the end thereof the following: ", or (C) providing increased emphasis on the ethical, social, legal, and moral implications of advances in biomedical research and technology with respect to the effects of such advances on individuals and society".

Approved July 12, 1974.

ETHICS ADVISORY BOARD

Provisions governing the Ethics Advisory Board derive from volume 45, part 46, subpart B, of the Code of Federal Regulations (CFR) and the two charters under which it operated from 1978-80. The pertinent CFR sections and charters are reproduced below. (The regulations refer to ''Ethical Advisory Boards,' but the body came to be known as the Ethics Advisory Board, as noted in the second charter.)

45 CFR, Subpart B—Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization

Section 46.201 Applicability.

(a) The regulations in this subpart are applicable to all Department of Health and Human Services grants and contracts supporting research, development, and related activities involving: (1) The fetus, (2) pregnant women, and (3) human *in vitro* fertilization.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in an way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

Section **46.202** Purpose.

It is the purpose of this subpart to provide additional safeguards in reviewing activities **to** which this subpart is applicable to assure that they conform **to** appropriate ethical standards and relate to important societal needs.

Section 46.203 Definitions.

As used in this subpart:

(a) "Secretary' means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) "Pregnancy" encompasses the period of time from confirmation of implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.

(c) "Fetus" means the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until a determination is made, following expulsion or extraction of the fetus, that it is viable.

(d) "Viable" as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the *Federal Register* guidelines to assist in determining whether a fetus is viable for purposes of this subpart. If a fetus is viable after delivery, it is a premature infant.

(e) "Nonviable fetus" means a fetus ex *utero* which, although living, is not viable.

(f) "Dead fetus" means a fetus ex *utero* which exhibits neither heartbeat, spontaneous respiratory **activity,** spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if **still attached).**

(g) ''h vitro fertilization" means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.

Section 46.204 Ethical Advisory Boards.

(a) One or more Ethical Advisory Boards shall be established by the Secretary. Members of these board(s) shall be so selected that the board(s) will be competent to deal with medical, legal, social, ethical, and related issues and may include, for example, research scientists, physicians, psychologists, sociologists, educators, lawyers, and

ethicists, as well as representatives of the general public. No board member maybe a regular, full-time employee of the Department of Health and Human Services.

(b) At the request of the Secretary, the Ethical Advisory Board shall render advice consistent with the policies and requirements of this part as to ethical issues, involving activities covered by this subpart, raised by individual applications or proposals. In addition, upon request by the Secretary, the Board shall render advice as to classes of applications or proposals and general policies, guidelines, and procedures.

(c) A Board may establish, with the approval of the Secretary, classes of applications or proposals which: (1) Must be submitted to the Board, or (2) need not be submitted to the Board. Where the Board so establishes a class of applications or proposals which must be submitted, no application or proposal within the class may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

(d) No application or proposal involving human *in vitro* fertilization maybe funded by the Department of any component thereof until the application or proposal has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

THE SECRETARY OF HEALTH, EGUCATION, AND WELFARE
WASHINGTON. D. C 2020 I

CHARTER

ETHICAL ADVISORY BOARD

Purpose

In the Federal Register of August 8, 1975 (40 FR 33526) , the Secretary of Health, Educaticn, and Welfare published regulations regarding research, development, and related activities involving fetuses, pregnant women, and in vitro fertilization. The regulations, codified at 45 CFR Part 46, Subpart B, provide for the establishment by the Secretary of one or more Ethical Advisory Boards. Review of the current needs for such an advisory structure indicates that, for the time being, a single Board may be sufficient to meet the Department's needs. This Board will advise the Department regarding biomedical and behavioral research activities covered by Subpart B, in accordance with the provisions thereof. In addition, the Board will advise the Secretary, as requested, with respect to issues arising under Section 474 (b) of the Public Health Service Act, as amended (42 U.S.C. 2891-3) The Board may also be assigned responsibility for advising with-respect to ethical issues raised by other Departmental biomedical and behavioral research activities subject to the provisions of 45 CFR 46.

Authority

42 U.S. Code 217a. This Board is governed by the provisions of Public Law 92-463 which sets forth standards for the formation and use of advisory committees

Function

At the request of the Secretary or his designee, the Ethical Advisory Board shall render advice consistent with the policies and *requirements* of 45 CFR Part **46,** *Subpart B as to etihical issues, involving* activities **covered by** that subpart, raised by individual applications or proposals. In addition, upon request by the Secretary or his designee, the Board shall render advice as to classes of applications or proposals and general policies, guidelines, and procedures under Subpart B.

The Board may establish, with the approval of the Secretary or his designee, classes of applications or proposals involving activities revered by Subpart B which: (1) must be submitted to the Board, or (2) need not be submitted to the Board. Where the Board so establishes a class of applications or proposals which must be submitted, no application or proposal within the class may be funded by the Department of Health, Education, and Welfare or any component thereof until the application or proposal has been reviewed by the Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

No application or proposal involving human in vitro fertilization may be funded by the Department of Health, Education, and Welfare or any component thereof until the application or proposal has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

The Board must approve a request by the applicant or offeror to modify or waive requirements of Subpart B, in order for the secretary or his designee to grant such a request.

At the request of the Secretary or his designee, the Board will provide advice with respect to issues arising under Section 474 (b) of the Public Health Service Act, as amended (42 U.S.C. 2891-3).

The Secretary or his designee may assign the Board responsibility for advising the Department of Health, Education, and Welfare regarding ethical issues raised by other Department of Health, Education, and Welfare activities subject to the provisions of 45 CFR 46.

Structure

The Ethical Advisory Board shall consist of fourteen members , including the Chairman, appointed by the Secretary or his designee. Members shall be so selected that the Board will be competent to deal with medical, legal, social, ethical, and related beomedical issues, provided that: (1) no more than seven may be Scientists, of whom four shall be beomedical scientists and three social or behavioral scientists; and (2) the remainder shall be from other disciplines or representatives of the general public, except that at least one shall be an attorney and one shall be an ethicist. No Board member may be a regular, full-time employee of the Federal government.

Members shall be invited to seine for overlapping four-year terms, except that of these persons initially appointed to the Board, four shall be appointed for four-year terms, four for three-year terms, three for two-year terns, and three for one-year terns. Terms of more than two years are contingent upon renewal of the Board by appropriate action prior to its termination.

Management and staff services shall be provided by the Executive Secretary of the Ethical Advisory Board, Office of the Director, National Institutes of Health.

Meetings

Meetings will usually be held three tires a year or at the call of the chairman with the advance approval of a government official who shall also approve the agenda. A government official shall be present at all meetings .

Meetings shall be open to the public except as determined otherwise by the Secretary or his designee; notice of all meetings shall be *given to the* public.

Meetings shall be conducted, and records of proceeding kept, as required by applicable laws and Departmental regulations.

Decisions of the Board on matters of broad public interest shall be published in such form and manner as the Secretary may approve.

Compensation

Members shall be paid at the rate of $100 per day plus per diem and travel expenses in accordance with Standard Government Travel Regulations.

Annual Cost Estimate

Estimated annual cost for operating the Board, including compensation and travel expenses but excluding staff support , is $50,000. Estimate of annual person years of staff support required is two, at a cost of *$40,000.*

Report

An annual report shall be submitted to the Secretary **and** the Assistant Secretary for Health not later than 60 days following the beginning of the next fisca1 year which shall contain, as a minimum, a list of members and their business addresses, the Committee's **functions, the dates and** places of meetings, and a summary of the Committee's activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

Termination Date

Unless renewed by appropriate action prior to its expiration, the Ethical Advisory Board will terminate two years from the date this charter is approved, or, if earlier, the first day of the first month that follows the date on which all the members of the National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research (as provided for by Section 211 of the National Research Act) are appointed.

APPROVED :

DEC 271976
Date

Secretary

THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE

WASHINGTON, D. C. 2020 [

CHARTER

ETHICS ADVISORY BOARD

Purpose

The Ethics Advisory Board will *review* and advise the Secretary, as requested, with respect to the ethics of current and proposed departmental research and other activities, and of the missions, programs, agency assignments, or procedures that are proposed to, or are reviewed, supported, conducted, sponsored, monitored, or regulated by the Department or which may involve the Department directly or indirectly through other Federal, domestic, foreign, or international organizations, institutions, agencies or persons.

Department regulations (45 CFR 46) for the protection of human subjects involved in research, development or related activities conducted, supported, or sponsored by the Department provide for the establishment of one or more Ethics Advisory Boards within the Department. Review of the current needs for the prescribed functions indicates that, for the time being, a single Board may be sufficient to meet the Department's needs. This Board will advise the Department regarding research activities covered by applicable subparts and sections of 45 CFR 46, in accordance with the provisions thereof. In addition, the Board will advise the Secretary, as requested, with respect to issues arising under Section 474(b) of the Public Health Service Act, as amended (42 U.S.C. 2891-3).

The Board may initiate inquiries, hold hearings and conduct public meetings, symposia, or other means for the purpose of developing appropriate recommendations and to advise the Secretary.

Authority

42 U.S. Code 217a. This Board is governed by the provisions of Public Law 92-463 as amended which sets forth standards for the formation and use of advisory committees.

Functions

1. At the request of the Secretary, the Ethics Advisory Board shall advise, consult with, and make recommendations to the Secretary regarding the ethics of any research or other policy, or any mission, program, agency assignment, or activity.

2. The Board may conduct inquiries and hold hearings on proposed policies and regulations and on the interpretation, applicability, administration, and effectiveness of departmental regulations, policies or requirements and on the implementation of safeguards and assurances by institutions or by agencies within the Department for the purpose of protecting the rights and welfare of human subjects, or on **other ethical** matters and will report its findings and recommendations to the Secretary.

3. At the request of the Secretary, the Board will provide advice on ethical issues addressed to the Secretary regarding research, development or related activities involving human subjects.

4. The Board may advise, consult with and make recommendations to the Secretary on ethical **issues** that arise in regard to proposed or ongoing research, development or related activities involving human subjects that may be conducted, supported, sponsored or regulated by the Department.

5. The Board may consider appeals, requests and inquiries from Institutional Review Boards or comparable agency review committees that are addressed to the Secretary for guidance on ethical or policy questions regarding research activities or proposals involving human subjects when **such referrals,** in the judgment of the Secretary, present substantive ethical or related policy issues.

6. The Chairman of the Board shall report directly to the Secretary on all proposed agenda subjects, actions and recommendations of the Board on policy development or policy review matters.

Ethical reviews required by regulation or referred to or requested by the Board on specific proposals or ongoing activities will be reported through the Office of the Secretary to the head of the departmental agency or agencies involved.

Structure

The Ethics Advisory Board shall consist of no less than fourteen nor more than twenty members, including the Chairman, appointed by the Secretary.

Selection of members shall be made for representation from the legal, ethical, scientific, medical and social professions or from the general public, with special qualifications and competence to deal effectively

with ethical issues of concern to the Department, provided that at least one member shall be an attorney, at least one member shall be an ethicist, at least one member shall be a practicing physician, at least one member shall be a theologian, and that no less than one-third nor More than half the total membership shall be career scientists with substantial research accomplishments, each to be selected for competency in one or more of the following categories; (a) basic biomedical and behavioral (e.g. , physiological, genetic, psychological, pathological or etiological) research; (b) pediatrics, developmental human biology, obstetrical or gynecological research; (c) epidemiology, population or health services research; (d) psychiatric, clinical psychology, behavioral or socio-logical research; and (e) design and conduct of large scale clinical research programs **for improving** the **treatment of major** diseases or disorders.

No Board member may be a regular, **full** time employee of the Federal government.

Members shall be appointed **for four** year terms except that of the members first appointed, approximately one fourth shall be appointed for terms of one year, one fourth for terms of two years, one fourth for terms of three years, and one fourth for terms of four years.

Any member appointed to fill a vacancy occurring prior to expiration of the term for which his predecessor was appointed shall serve for the remainder of such term. Appointed members shall be eligible for reappointment for one additional four year term. Members may serve after the expiration of their terms until their successors have taken office.

A majority of the appointed members shall constitute a quorum of the Board.

The Board may refer specific questions, problems, and issues to any other Departmental committee, agency or staff for advice and counsel .

On recommendations by the Board, the Secretary may approve the issuance of requests for proposals and make sole or multiple contracts for personal or institutional services for consultants to the Board, *to* sponsor or conduct appropriate meetings, workshops, symposia, studies or investigations and for preparation of transcripts, reports, and other documents to assist the Board in its assigned functions.

The Board is empowered to have access to all records within the Department and to all records outside the Department available to the Secretary under the provisions of 45 CFR 46, or as may be additionally authorized by the Secretary or his designee.

Management and staff services shall be provided by the Office of the Director, National Institutes of Health. The Chairman of the Board, **after consultation with the Board,** shall **appoint a Staff Director and a Deputy Staff Director. Additional staff shall be appointed by the Staff Director.** The Office of the Secretary, HEW, will, as justified and necessary, on request of the Chairman and with concurrence by the Secretary, authorize detail assignments of staff from departmental agencies to the staff of the Board. The Staff Director may enter into contracts for the purpose of assisting the Board in the performance of its functions.

Meetings

The Board may hold **up** to ten meetings a year or at the call of the Chairman. Subcommittee meetings may also be held three to six times a year. All meetings require advance approval by an authorized government official who shall also approve the agenda. An authorized government official shall be present at all meetings.

Meetings shall be conducted, and records of proceedings kept, as required by applicable laws and departmental regulations.

Compensation

Members shall be paid at the rate of $182.72 per day plus **per diem and travel** expenses in accordance with Standard Government Travel Regulations.

Annual Cost Estimate

The estimated annual cost **for the operations and functions of the Board including compensation, travel expenses and contract** services but excluding staff support is estimated at $1,000,000. The estimated annual person years of staff support is ten, at a cost of approximately $270,000.

Report

An annual report shall be submitted to the Secretary no later than 60 days following the beginning of the next fiscal year which shall contain, as a minimum, a list of members and their business addresses, the Board's functions, the dates and places of meetings, and a summary of the Board's activities and recommendations made during the fiscal year. A **COPY Of** the report shall be provided to the Department Committee Management Officer.

Termination Date

Unless renewed by appropriate action prior to its expiration, the Ethics Advisory Board will terminate two years from the date this Charter is approved.

APPROVED:

JAN 11 1979

Date

Secretary

PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH

Public Law 95-622 authorized creation of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Although not fully operational during the entire period, the authority for the President's Commission was 1978-83. Reprinted below is the relevant section of the U.S. Code.

42 U.S.C. Subchapter XVI—Presiden's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research

Section 300 v. Commission

(a) Establishment; composition; appointment of members; vacancies

(1) There is established the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (hereinafter in this subchapter referred to as the 'Commission') which shall be composed of eleven members appointed by the President. The members of the Commission shall be appointed as follows:

(A) Three of the members shall be appointed from individuals who are distinguished in biomedical or behavioral research.

(B) Three of the members shall be appointed from individuals who are distinguished in the practice of medicine or otherwise distinguished in the provision of health care.

(C) Five of the members shall be appointed from individuals who are distinguished in one or more of the fields of ethics, theology, law, the natural sciences (other than a biomedical or behavioral science), the social sciences, the humanities, health administration, government, and public affairs.

(2) No individual who is a full-time officer or employee of the United States may be appointed as a member of the Commission. The Secretary of Health and Human Services, the Secretary of Defense, the Director of Central Intelligence, the Director of the Office of Science and Technology Policy, the Administrator of Veteran's Affairs, and the Director of the National Science Foundation shall each designate an individual to provide liaison with the Commission.

(3) No individual maybe appointed to serve as a member of the Commission if the individual has served for two terms of four years each as such a member.

(4) A vacancy in the Commission shall be filled in the manner in which the original appointment was made.

(b) Terms of members

(1) Except as provided in paragraphs (2) and (3), members shall be appointed for terms of four years.

(2) Of the members first appointed—

(A) four shall be appointed for terms of three years, and

(B) three shall be appointed for terms of two years, as designated by the President at the time of appointment.

(3) Any member appointed to fill a vacancy occurring before the expiration of the term for which his predecessor was appointed shall be appointed only for the remainder of such term. A member may serve after the expiration of his term until his successor has taken office.

(c) Chairman

The chairman of the Commission shall be appointed by the President, by and with the advice and consent of the Senate, from members of the Commission.

(d) Meetings

(1) Seven members of the Commission shall constitute a quorum for business, but a lesser number may conduct hearings.

(2) The Commission shall meet at the call of the chairman or at the call of a majority of its members.

(e) Compensation; travel expenses, etc.

(1) Members of the Commission shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule for each day (including travel time) during which they are engaged in the actual performance of duties vested in the Commission.

(2) While away from their homes or regular places of business in the performance of services for the Commission, members of the Commission shall be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in the Government service are allowed expenses under section 5703 of Title 5.

Section 300 v-1. Duties of Commission

(a) Studies and investigation; priority and order; report to President and Congress

(1) The Commission shall undertake studies of the ethical and legal implications of—

(A) the requirements for informed consent to participation in research projects and to otherwise undergo medical procedures;

(B) the matter of defining death, including the advisability of developing a uniform definition of death;

(C) voluntary testing, counseling, and information and education programs with respect to genetic diseases and conditions, taking into account the essential quality of all human beings, born and unborn;

(D) the differences in the availability of health services as determined by the income or residence of the persons receiving the services;

(E) current procedures and mechanisms designed (i) to safeguard the privacy of human subjects of behavioral and biomedical research, (ii) to ensure the confidentiality of individually identifiable patient records, and (iii) to ensure appropriate access of patients to information continued [sic] in such records, and

(F) such other matters relating to medicine or biomedical or behavioral research as the President may designate for study by the Commission.

The Commission shall determine the priority and order of the studies required under this paragraph.

(2) The Commission may undertake an investigation or study of any other appropriate matter which relates to medicine or biomedical or behavioral research (including the protection of human subjects of biomedical or behavioral research) and which is consistent with the purposes of this subchapter on its own initiative or at the request of the head of a Federal agency.

(3) In order to avoid duplication of effort, the Commission may, in lieu of, or as part of, any study or investigation required or otherwise conducted under this subsection, use a study or investigation conducted by another entity if the Commission sets forth its reasons for such use.

(4) Upon the completion of each investigation or study undertaken by the Commission under this subsection (including a study or investigation which merely uses another study or investigation), it shall report its findings (including any recommendations for legislation or administrative action) to the President and the Congress and to each Federal agency to which a recommendation in the report applies.

(b) Recommendations to agencies; subsequent administrative requirements

(1) 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.

(2) 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.

(c) Report on protection of human **subjects; scope; submission to President, etc.**

The Commission shall biennially report to the President, the Congress, and appropriate Federal agencies on the protection of human subjects of biomedical and behavioral research. Each such report shall include a review of the adequacy and uniformity (1) of the rules, policies, guidelines, and regulations of all Federal agencies regarding the protection of human subjects of biomedical or behavioral research which such agencies conduct or support, and (2) of the implementation of such rules, policies, guidelines, and regulations by such agencies, and may include such recommendations for legislation and administrative action as the Commission deems appropriate.

(d) Annual report; scope; submission to President, etc.

Not later than December 15 of each year (beginning with **1979) the** Commission shall report to the President, the Congress, and appropriate Federal agencies on the activities of the Commission during the fiscal year ending in such year. Each such report shall include a complete list of all recommendations described in subsection (b)(1) of this section made to Federal agencies by the Commission during the fiscal year and the actions taken, pursant [sic] to subsection (b)(2) of this section, by the agencies upon such recommendations, and may include such recommendations for legislation and administrative action as the Commission deems appropriate.

(e) Publication and dissemination of reports

The Commission may at any time publish and disseminate to the public reports respecting its activities.

(f) Definitions

For purposes of this section:

(1) The term "Federal agency" means an authority of the government of the United States, but does not include (A) the Congress, (B) the courts of the United States, and (C) the government of the Commonwealth of Puerto Rico, the government of the District of Columbia, or the government of any territory or possession of the United States.

(2) The term "protection of human subjects '' includes the protection of the health, safety, and privacy of individuals.

Section **300 v-2. Administrative provisions**

(a) Hearings

The Commission may for the purpose of carrying out this subchapter hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence, as the Commission may deem advisable.

(b) Appointment and compensation of staff personnel; procurement and compensation of temporary and intermittent services; detail of personnel from other Federal agencies

(1) 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 governing appointments in the competitive service, and shall be paid in accordance with the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

(2) The Commission may procure temporary and intermittent services to the same extent as is authorized by section 3109(b) of Title 5, but at rates for individuals not to exceed the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule.

(3) 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 subchapter.

(c) Contracting authority

The Commission, in performing its duties and functions under this subchapter, may enter into contracts with appropriate public or nonprofit private entities. The authority of the Commission to enter into such contracts is effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

(d) **Information** requirements and prohibitions

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

(2) 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 subchapter.

(3) 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 by reason of paragraphs (4) and (6) of subsection (b) of such section.

(e) Support services from Administrator of General Services

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

Section `300 v-3.` Authorization of appropriations; termination of Commission

(a) To carry out this subchapter there are authorized to be appropriated $5,000,000 for the fiscal year ending September 30, 1979, $5,000,000 for the fiscal year ending September 30, 1980, $5,000,000 for the fiscal year ending September 30, 1981, and $5,000,000 for the fiscal year ending September 30, 1982.

(b) The Commission shall be subject to the Federal Advisory Committee Act, except that, under section lo of such Act, the Commission shall terminate on December 31, 1982.

BIOMEDICAL ETHICS BOARD AND BIOMEDICAL ETHICS ADVISORY COMMIITEE

In 1985, Congress passed, and the President signed, Public Law 99-158, which included establishment of a congressional Biomedical Ethics Board and the appointment of the Biomedical Ethics Advisory Committee. Both entities ceased to exist in 1989, having been operational for approximately 16 months. Reprinted below is the relevant section of the U.S. Code.

42 U.S.C. Section 275. Biomedical Ethics Board

(a) Establishment

There is established in the legislative branch of the Government the Biomedical Ethics Board (hereinafter referred to as the "Board").

(b) Membership; term of office; vacancies; chairman and vice chairman; meetings

(1) The Board shall consist of twelve members as follows:

(A) Six Members of the Senate appointed as follows: Three members appointed by the Majority Leader of the Senate from the majority party and three members appointed by the Minority Leader from the minority party.

(B) Six Members of the House of Representatives appointed by the Speaker of the House of Representatives, three from the majority party and three from the minority party.

(2) The term of office of a member of the Board shall expire when the member leaves the office of Senator or Representative; as the case may be, or upon the expiration of eight years after the date of the member's appointment to the Board, whichever occurs first.

(3) Vacancies in the membership of the Board shall not affect the power of the remaining members to execute the functions of the Board and shall be filled in the same manner as in the case of the original appointment.

(4) The Board shall select a chairman and a vice chairman from among its members at the beginning of each Congress. The vice chairman shall act as chairman in the absence of the chairman or in the event of the incapacity of the chairman. The chairmanship and vice chairmanship shall alternate between the Senate and the House of Representatives with each Congress. The chairman during each even-numbered Congress shall be selected by the Members of the House of Representatives on the Board from among their number. The vice chairman during each Congress shall be chosen in the same manner from that House of Congress other than the House of Congress of which the chairman is a Member.

(5) The Board shall meet once every three months unless such meeting is dispensed with by the chairman, and may meet at any time upon the request of four or more members of the Board or upon the call of the chairman.

(c) Functions; annual report to Congress; report to the Congress on research and developments in genetic engineering

(1) The Board shall study and report to the Congress on a continuing basis on the ethical issues arising from the delivery of health care and biomedical and behavioral research, including the protection of human subjects of such research and developments in genetic engineering (including activities in recombinant DNA technology) which have implications for human genetic engineering.

(2)(A) Except as provided in subparagraph (B), an annual report shall be transmitted to the Congress identifying the issues which were the subject of the study conducted under paragraph (1) and identifying areas, programs, and practices of medicine and biomedical and behavioral research which have significant ethical implications and which would be appropriate subjects for study.

(B) A report on research and developments in genetic engineering (including activities in recombinant DNA technology) which have implications for human genetic engineering shall be transmitted to the Congress not later than eighteen months after the appointment of the Committee under subsection (d) of this section.

(d) Biomedical Ethics Advisory Committee; appointment, membership, compensation, etc.; functions; public hearings; availability of additional personnel and information; gifts and donations; use of mails

(1) To conduct the studies and make the reports required by subsection (c) of this section, the Board shall appoint a Biomedical Ethics Advisory Committee (hereinafter referred to as the "Committee"). The Committee shall consist of fourteen members as follows:

(A) Four of the members shall be appointed by the Board from individuals who are distinguished in biomedical or behavioral research,

(B) Three of the members shall be appointed by the Board from individuals who are distinguished in the practice of medicine or otherwise distinguished in the provision of health care.

(C) Five of the members shall be appointed by the Board from individuals who are distinguished in one or more of the fields of ethics, theology, law, the natural sciences (other than the biomedical or behavioral sciences), the social sciences, the humanities, health administration, government, and public affairs.

(D) Two of the members shall be appointed by the Board from individuals who are representatives of citizens with an interest in biomedical ethics but who possess no specific expertise.

(2)(A) The Committee, by majority vote, shall elect from its members a chairman and a vice chairman and appoint an executive director who shall serve for such time and under such conditions as the Committee may prescribe. In the absence of the chairman, or in the event of the incapacity of the chairman, the vice chairman shall act as chairman.

(B) The term of office of each member of the Committee shall be four years, except that any such member appointed to fill a vacancy occurring prior to the expiration of the term for which such member's predecessor was appointed shall be appointed for the remainder of such term. Terms of the members shall be staggered so as to establish a rotating membership.

(C) The members of the Committee shall receive no pay for their services as members of the Committee, but shall be allowed necessary travel expenses (or, in the alternative, mileage for use of privately owned vehicles and a per diem of subsistence at not to exceed the rate prescribed in sections 5702 and 5704 of Title 5) and other necessary expenses incurred by them in the performance of duties as a member of the Committee, without regard to the provisions of subchapter 1 [sic] of chapter 57 and section 5731 of Title 5, and regulations promulgated thereunder.

(D) The executive director of the Committee, with the approval of the Committee, may employ such staff and consultants as necessary to prepare studies and reports for the Committee.

(3)(A) The Committee may, for the purpose of carrying out its functions, hold such public hearings, sit and act at such times and places, and take such testimony, as the Committee considers appropriate.

(B) Upon request of the Committee, the head of any Federal agency is authorized to detail, on a reimbursable basis, any of the personnel of such agency to the Committee to assist the Committee in carrying out its functions.

(C) The Committee may secure directly from any department or agency of the United States information necessary to enable it to carry out its functions. Upon request of the chairman of the Committee, the head of such department or agency shall furnish such information to the Committee.

(D) The Committee may accept, use, and dispose of gifts or donations or services or property.

(E) The Committee may use the United States mails in the same manner and under the same conditions as other departments and agencies of the United States.

(e) Authorization of appropriations

To enable the Board and the Committee to carry out their functions there are authorized to be appropriated $2,000,000 for fiscal year 1986,$2,500,000 for fiscal year 1987,$3,000,000 for fiscal year 1988,$2,000,000 for fiscal year 1989, and $2,500,000 for fiscal year 1990.