Public Law 93-348

July 12, 1974
[H. R. 7724]

AN ACT

To amend the Public Health Service Act to establish a program of National Research Service Awards to assure the continued excellence of biomedical and behavioral research and to provide for the protection of human subjects involved in biomedical and behavioral research and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

National Research Act.
42 USC 289*l*-1 note.

SECTION 1. This Act may be cited as the "National Research Act".

TITLE I—BIOMEDICAL AND BEHAVIORAL RESEARCH TRAINING

National Research Service Award Act of 1974.

SHORT TITLE

42 USC 289*l*-1 note.

SEC. 101. This title may be cited as the "National Research Service Award Act of 1974".

FINDINGS AND DECLARATION OF PURPOSE

42 USC 289*l*-1 note.

SEC. 102. (a) Congress finds and declares that—

(1) the success and continued viability of the Federal biomedical and behavioral research effort depends on the availability of excellent scientists and a network of institutions of excellence capable of producing superior research personnel;

(2) direct support of the training of scientists for careers in biomedical and behavioral research is an appropriate and necessary role for the Federal Government; and

(3) graduate research assistance programs should be the key elements in the training programs of the institutes of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration.

(b) It is the purpose of this title to increase the capability of the institutes of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration to carry out their responsibility of maintaining a superior national program of research into the physical and mental diseases and impairments of man.

BIOMEDICAL AND BEHAVIORAL RESEARCH TRAINING

Ante, p. 135.

SEC. 103. The part H of the Public Health Service Act relating to the appointment of the Directors of the National Institutes of Health and the National Cancer Institute is redesignated as part I, section 461 of such part is redesignated as section 471, and such part is amended by adding at the end the following new sections:

"NATIONAL RESEARCH SERVICE AWARDS

42 USC 289*l*-1.

"SEC. 472. (a)(1) The Secretary shall—

"(A) provide National Research Service Awards for—

"(i) biomedical and behavioral research at the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration in matters relating to the cause, diagnosis, prevention, and treatment of the disease (or diseases) or other health problems to which the activities of the Institutes and Administration are directed,

"(ii) training at the Institutes and Administration of individuals to undertake such research,

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"(iii) biomedical and behavioral research at non-Federal public institutions and at nonprofit private institutions, and

"(iv) pre- and postdoctoral training at such public and private institutions of individuals to undertake such research; and

"(B) make grants to non-Federal public institutions and to nonprofit private institutions to enable such institutions to make to individuals selected by them National Research Service Awards for research (and training to undertake such research) in the matters described in subparagraph (A)(i). Non-Federal public and nonprofit private institutions, grants.

A reference in this subsection to the National Institutes of Health or the Alcohol, Drug Abuse, and Mental Health Administration shall be considered to include the institutes, divisions, and bureaus included in the Institutes or under the Administration, as the case may be.

"(2) National Research Service Awards may not be used to support residencies. Prohibition.

"(3) Effective July 1, 1975, National Research Service Awards may be made for research or research training in only those subject areas for which, as determined under section 473, there is a need for personnel. *Post*, p. 345.

"(b)(1) No National Research Service Award may be made by the Secretary to any individual unless—

"(A) the individual has submitted to the Secretary an application therefor and the Secretary has approved the application; Application.

"(B) the individual provides, in such form and manner as the Secretary shall by regulation prescribe, assurances satisfactory to the Secretary that the individual will meet the service requirement of subsection (c)(1); and

"(C) in the case of a National Research Service Award for a purpose described in subsection (a)(1)(A)(iii) or (a)(1)(A)(iv), the individual has been sponsored (in such manner as the Secretary may by regulation require) by the institution at which the research or training under the Award will be conducted.

An application for an Award shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe.

"(2) The award of National Research Service Awards by the Secretary under subsection (a) and the making of grants for such Awards shall be subject to review and approval by the appropriate advisory councils to the entities of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration (A) whose activities relate to the research or training under the Awards, or (B) at which such research or training will be conducted. Review.

"(3) No grant may be made under subsection (a)(1)(B) unless an application therefor has been submitted to and approved by the Secretary. Such application shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe. Subject to the provisions of this section other than paragraph (1) of this subsection, National Research Service Awards made under a grant under subsection (a)(1)(B) shall be made in accordance with such regulations as the Secretary shall prescribe. Application approval.

"(4) The period of any National Research Service Award made to any individual under subsection (a) may not exceed three years in the aggregate unless the Secretary for good cause shown waives the application of the three-year limit to such individual. Three-year limitation.

Stipends and allowances.

"(5) National Research Service Awards shall provide for such stipends and allowances (including travel and subsistence expenses and dependency allowances) for the recipients of the Awards as the Secretary may deem necessary. A National Research Service Award made to an individual for research or research training at a non-Federal public or nonprofit private institution shall also provide for payments to be made to the institution for the cost of support services (including the cost of faculty salaries, supplies, equipment, general research support, and related items) provided such individual by such institution. The amount of any such payments to any institution shall be determined by the Secretary and shall bear a direct relationship to the reasonable costs of the institution for establishing and maintaining the quality of its biomedical and behavioral research and training programs.

Health research or teaching, participation.

"(c)(1)(A) Each individual who receives a National Research Service Award shall, in accordance with paragraph (3), engage in—

"(i) health research or teaching,

"(ii) if authorized under subparagraph (B), serve as a member of the National Health Service Corps or serve in his specialty, or

"(iii) if authorized under subparagraph (C), serve in a health related activity approved under that subparagraph,

for a period computed in accordance with paragraph (2).

"(B) Any individual who received a National Research Service Award and who is a physician, dentist, nurse, or other individual trained to provide health care directly to individual patients may, upon application to the Secretary, be authorized by the Secretary to—

"(i) serve as a member of the National Health Service Corps,

"(ii) serve in his specialty in private practice in a geographic area designated by the Secretary as requiring that specialty, or

"(iii) provides services in his specialty for a health maintenance organization to which payments may be made under section 1876 of title XVIII of the Social Security Act and which serves a medically underserved population (as defined in section 1302(7) of this Act),

42 USC 1395mm.

42 USC 300e-1.

in lieu of engaging in health research or teaching if the Secretary determines that there are no suitable health research or teaching positions available to such individual.

Health-related activities.

"(C) Where appropriate the Secretary may, upon application, authorize a recipient of a National Research Service Award, who is not trained to provide health care directly to individual patients, to engage in a health-related activity in lieu of engaging in health research or teaching if the Secretary determines that there are no suitable health research or teaching positions available to such individual.

"(2) For each year for which an individual receives a National Research Service Award he shall—

"(A) for twelve months engage in health research or teaching or, if so authorized, serve as a member of the National Health Service Corps, or

"(B) if authorized under paragraph (1)(B) or (1)(C), for twenty months serve in his specialty or engage in a health-related activity.

"(3) The requirement of paragraph (1) shall be complied with by any individual to whom it applies within such reasonable period of time, after the completion of such individual's Award, as the Secretary shall by regulation prescribe. The Secretary shall (A) by regulation prescribe (i) the type of research and teaching which an individual may engage in to comply with such requirement, and (ii)

such other requirements respecting such research and teaching and alternative service authorized under paragraphs (1)(B) and (1)(C) as he deems necessary; and (B) to the extent feasible, provide that the members of the National Health Service Corps who are serving in the Corps to meet the requirement of paragraph (1) shall be assigned to patient care and to positions which utilize the clinical training and experience of the members.

Noncompliance, recovery formula.

"(4)(A) If any individual to whom the requirement of paragraph (1) is applicable fails, within the period prescribed by paragraph (c), to comply with such requirement, the United States shall be entitled to recover from such individual an amount determined in accordance with the formula—

$$A=\phi\left(\frac{t-1/2s}{t}\right)$$

in which 'A' is the amount the United States is entitled to recover; 'ϕ' is the sum of the total amount paid under one or more National Research Service Awards to such individual and the interest on such amount which would be payable if at the time it was paid it was a loan bearing interest at a rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing at the time each Award to such individual was made; 't' is the total number of months in such individual's service obligation; and 's' is the number of months of such obligation served by him in accordance with paragraphs (1) and (2) of this subsection.

"(B) Any amount which the United States is entitled to recover under subparagraph (A) shall, within the three-year period beginning on the date the United States becomes entitled to recover such amount, be paid to the United States. Until any amount due the United States under subparagraph (A) on account of any National Research Service Award is paid, there shall accrue to the United States interest on such amount at the same rate as that fixed by the Secretary of the Treasury under subparagraph (A) to determine the amount due the United States.

Obligations, cancellation, waiver or suspension.

"(4)(A) Any obligation of any individual under paragraph (3) shall be canceled upon the death of such individual.

"(B) The Secretary shall by regulation provide for the waiver or suspension of any such obligation applicable to any individual whenever compliance by such individual is impossible or would involve extreme hardship to such individual and if enforcement of such obligation with respect to any individual would be against equity and good conscience.

Appropriation.

"(d) There are authorized to be appropriated to make payments under National Research Service Awards and under grants for such Awards $207,947,000 for the fiscal year ending June 30, 1975. Of the sums appropriated under this subsection, not less than 25 per centum shall be made available for payments under National Research Service Awards provided by the Secretary under subsection (a)(1)(A).

"STUDIES RESPECTING BIOMEDICAL AND BEHAVIORAL RESEARCH PERSONNEL

42 USC 289*l*-2.

"SEC. 473. (a) The Secretary shall, in accordance with subsection (b), arrange for the conduct of a continuing study to—

"(1) establish (A) the Nation's overall need for biomedical and behavioral research personnel, (B) the subject areas in which such personnel are needed and the number of such personnel needed in each such area, and (C) the kinds and extent of training which should be provided such personnel;

"(2) assess (A) current training programs available for the training of biomedical and behavioral research personnel which are conducted under this Act at or through institutes under the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration, and (B) other current training programs available for the training of such personnel;

"(3) identify the kinds of research positions available to and held by individuals completing such programs;

"(4) determine, to the extent feasible, whether the programs referred to in clause (B) of paragraph (2) would be adequate to meet the needs established under paragraph (1) if the programs referred to in clause (A) of paragraph (2) were terminated; and

"(5) determine what modifications in the programs referred to in paragraph (2) are required to meet the needs established under paragraph (1).

"(b)(1) The Secretary shall request the National Academy of Sciences to conduct the study required by subsection (a) under an arrangement under which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary. If the National Academy of Sciences is willing to do so, the Secretary shall enter into such an arrangement with such Academy for the conduct of such study.

"(2) If the National Academy of Sciences is unwilling to conduct such study under such an arrangement, then the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study and prepare and submit the reports thereon as provided in subsection (c).

Report to congressional committees.

"(c) A report on the results of such study shall be submitted by the Secretary to the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Labor and Public Welfare of the Senate not later than March 31 of each year."

CONFORMING AMENDMENTS

42 USC 241.

SEC. 104. (a)(1) Section 301 of the Public Health Service Act is amended (A) by striking out paragraph (c); (B) by striking out in paragraph (d) "or research training" each place it occurs, "and research training programs", and "and research training program"; and (C) by redesignating paragraphs (d), (e), (f), (g), (h), and (i) as paragraphs (c), (d), (e), (f), (g), and (h), respectively.

Clinical training and instruction.
42 USC 242a.

(2)(A) Section 303(a)(1) of such Act is amended to read as follows:

"(1) to provide clinical training and instruction and to establish and maintain clinical traineeships (with such stipends and allowances (including travel and subsistence expenses and dependency allowances) for the trainees as the Secretary may deem necessary);".

(B) Section 303(b) of such Act is amended by inserting before the first sentence the following: "The Secretary may provide for training, instruction, and traineeships under subsection (a)(1) through grants to public and other nonprofit institutions.".

42 USC 282.

(3) Section 402(a) of such Act is amended (A) by striking out "training and instruction" in paragraph (3) and inserting in lieu thereof "clinical training and instruction", and (B) by striking out paragraph (4) and by redesignating paragraphs (5), (6), and (7) as paragraphs (4), (5), and (6), respectively.

42 USC 286a.

(4) Section 407(b)(7) of such Act is amended (A) by striking out

"and basic research and treatment", and (B) by striking out "where appropriate".

(5) Section 408(b)(3) of such Act is amended by inserting "clinical" before "training" each place it occurs. 42 USC 286b.

(6) Section 412(7) of such Act is amended by striking out "(1) establish and maintain" and all that follows down through and including "maintain traineeships" and inserting in lieu thereof ", provide clinical training and instruction and establish and maintain clinical traineeships". 42 USC 287a.

(7) Section 413(a)(7) is amended by inserting "clinical" before "programs". 42 USC 287b.

(8) Section 415(b) is amended by inserting before the period at the end of the last sentence thereof the following: "; and the term 'training' does not include research training for which fellowship support may be provided under section 472". 42 USC 287d.

(9) Section 422 of such Act is amended (A) by striking out paragraph (c) and by redesignating paragraphs (d), (e), and (f) as paragraphs (c), (d), and (e), respectively, and (B) by striking out "training and instruction and establish and maintain traineeships" in paragraph (e) (as so redesignated) and inserting in lieu thereof "clinical training and instruction and establish and maintain clinical traineeships". 42 USC 288a.

(10) Section 434(c)(2) of such Act is amended by inserting "(other than research training for which National Research Service Awards may be made under section 472)" after "training" the first time it occurs. 42 USC 289c-1.

(11) Sections 433(a), 444, and 453 of such Act are each amended by striking out the second sentence thereof. 42 USC 289c, 289g, 289k.

(12) The heading for part I of title IV of such Act (as so redesignated by section 103) is amended by striking out "ADMINISTRATIVE" and inserting in lieu thereof "GENERAL." *Ante*, p. 342.

(b) The amendments made by subsection (a) shall not apply with respect to commitments made before the date of the enactment of this Act by the Secretary of Health, Education, and Welfare for research training under the provisions of the Public Health Service Act amended or repealed by subsection (a). 42 USC 241 note.

SEX DISCRIMINATION

SEC. 105. Section 799A of the Public Health Service Act is amended by adding at the end thereof the following: "In the case of a school of medicine which— 42 USC 295h-9.

"(1) on the date of the enactment of this sentence is in the process of changing its status as an institution which admits only female students to that of an institution which admits students without regard to their sex, and

"(2) is carrying out such change in accordance with a plan approved by the Secretary,

the provisions of the preceding sentences of this section shall apply only with respect to a grant, contract, loan guarantee, or interest subsidy to, or for the benefit of such a school for a fiscal year beginning after June 30, 1979."

FINANCIAL DISTRESS GRANTS

SEC. 106. Section 773(a) of the Public Health Service Act is amended (1) by striking out "$10,000,000" and inserting in lieu thereof "$15,000,000", and (2) by striking out "1972" each place it occurs in the last sentence thereof and inserting in lieu thereof "1974". 42 USC 295f-3.

TITLE II—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

42 USC 289*l*-1 note.

SEC. 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").

Membership.

(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.

Term.

Compensation.

(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 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of the duties of the Commission.

5 USC 5332 note.

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

Travel expenses.

(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(b) of title 5 of the United States Code.

Chairman.

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

Personnel.

(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.

5 USC 101 *et seq.*

5 USC 5101, 5331, 5332 note.

(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:

42 USC 289*l*-1 note.

(1) (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.

Research involving human subjects, study; guideline development.

(B) In carrying out subparagraph (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.

Post, p. 352.

(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

Consent requirements.

Definitions.

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.

Protection mechanism, study.

(3) The Commission shall conduct an investigation and study to determine the need for 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.

Living fetus research, study.

(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.

Psychosurgery usage, study.

(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.

Definition.

Recommendations to Congress.

(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.

Post, p. 351.

SPECIAL STUDY

42 USC 289*l*-1 note.

SEC. 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 implications 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

SEC. 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. 42 USC 289*l*-1 note.

(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. Information disclosure, prohibition.

(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. Reports to President, Congress and HEW.

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

DUTIES OF THE SECRETARY

SEC. 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. 42 USC 289*l*-1 note. Publication in Federal Register.

PART B—MISCELLANEOUS

NATIONAL ADVISORY COUNCIL FOR THE PROTECTION OF SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

SEC. 211. (a) Section 217 of the Public Health Service Act is amended by adding at the end the following new subsection: 42 USC 218.

"(f)(1) There shall be established a National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research Establishment.

Membership.

(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 purpose 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.

5 USC 101 *et seq.*

Ante, p. 348.

Term.

Duties.

"(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.

5 USC app. I.

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

Effective date.
42 USC 218 note.

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

INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

SEC. 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

42 USC 289*l*-3.

"SEC. 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 grant or 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 may be 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.

Regulations.
42 USC 289*l*-3 note.

Ante, p. 352.

LIMITATION ON RESEARCH

SEC. 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 induced abortion of such fetus, unless such research is done for the purpose of assuring the survival of such fetus.

42 USC 289*l*-1 note.

INDIVIDUAL RIGHTS

SEC. 214. (a) Subsection (c) of section 401 of the Health Programs Extension Act of 1973 is amended (1) by inserting "(1)" 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:

42 USC 300a-7.

"(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—

Nondiscrimination.

"(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

42 USC 295f-2.

SEC. 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.

Public Law 93-349

July 12, 1974
[H. R. 29]

AN ACT

To provide for payments by the Postal Service to the Civil Service Retirement Fund for increases in the unfunded liability of the Fund due to increases in benefits for Postal Service employees, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 8348 of title 5, United States Code, is amended by adding at the end thereof the following new subsection:

Civil Service Retirement Fund.
Postal Service payments.

"(h)(1) Notwithstanding any other statute, the United States Postal Service shall be liable for that portion of any estimated increase in the unfunded liability of the Fund which is attributable to any benefits payable from the Fund to active and retired Postal Service officers and employees, and to their survivors, when the increase results from an employee-management agreement under title 39, or any administrative action by the Postal Service taken pursuant to law, which authorizes increases in pay on which benefits are computed.

39 USC 101 *et seq.*

Unfunded liability increase, determination.

"(2) The estimated increase in the unfunded liability, referred to in paragraph (1) of this subsection, shall be determined by the Civil Service Commission. The United States Postal Service shall pay the amount so determined to the Commission in thirty equal annual installments with interest computed at the rate used in the most recent valuation of the Civil Service Retirement System, with the first payment thereof due at the end of the fiscal year in which an increase in pay becomes effective.".

Repeal.

SEC. 2. (a) The last sentence of section 1005(d) of title 39, United States Code, is repealed.

(b) Section 1005(d) of title 39, United States Code, is amended by adding at the end thereof the following new sentence: "The Postal Service shall pay into the Civil Service Retirement and Disability Fund the amounts determined by the Civil Service Commission under section 8348(h) of title 5.".

Supra.

Effective date, exceptions.
39 USC 1005 note.

SEC. 3. The effective date of this Act shall be July 1, 1971, except that the Postal Service shall not be required to make (1) the payments due June 30, 1972, June 30, 1973, and June 30, 1974, attributable to pay increases granted by the Postal Service prior to July 1, 1973, until such time as funds are appropriated to the Postal Service for that purpose, and (2) the transfer to the Civil Service Retirement and Disability Fund required by title II of the Treasury, Postal Service, and General Government Appropriation Act, 1974, Public Law 93-143.

87 Stat. 513.

Approved July 12, 1974.